SPECIAL NEEDS POPULATION BASIC SCREENING SURVEY PROCESS REPORT 2008

Bureau of Family Health Services

Nevada State Health Division

Department of Health and Human Services

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Governor

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Department of Health and Human Services

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TABLE OF CONTENTS

Background

Preparation for the 2007 Basic Screening Survey (BSS) of the Special Needs Population (SNP) began in May of 2005 when the State Oral Health Advisory Committee (OHAC) established a workgroup to look at improving services for special needs populations. The OHAC workgroup began working with the Governor's Commission on Mental Health & Developmental Services in May of 2006. In the fall of 2006, this group collaborated with the Medical Education Council of Nevada (MECON) on a survey of all dentists with an active Nevada license. The survey included questions about treating special needs patients.

In April of 2007 the Oral Health Screening Coordinator (OHSC) and the Oral Health Biostatistician (OHB) met with the Special Needs Committee, a group of individuals interested in pursuing a BSS of the special needs population. The committee consisted of: four University of Nevada, Las Vegas (UNLV) School of Dental Medicine (SDM) faculty; one representative of the Nevada Dental Association (NDA); one member of the Governor's Commission on Mental Health & Developmental Services; the Program Manager of the Nevada State Health Division Oral Health Program; and the Director of Desert Regional Center (DRC), a facility that supports people with developmental disabilities in their efforts to live, work, and recreate in the community. The outcome from this meeting was a BSS of the special needs population, with the data collection being done by fourth year dental students from the UNLV SDM. The State Health Division Oral Health Program OHSC and OHB would provide assistance with organization and data analysis.

The Association of State and Territorial Dental Directors (ASTDD) *Basic Screening Surveys: An Approach to Monitoring Community Oral Health, 1999* was the guideline used for the screenings and data collection. These guidelines have been followed for the five previous BSS projects in Nevada. As in previous BSS data collection projects the decision was made to record data for each individual tooth rather than record a general notation of treated decay, untreated decay, and missing teeth. Unlike the previous BSS projects, the calibration was done using only a PowerPoint® presentation rather than using the presentation in conjunction with calibrating using the population to be screened.

Funding for this project was provided by the Centers for Disease Control and Prevention through the Chronic Disease Prevention and Health Promotion Programs Component 4: State-Based Oral Disease Prevention Program (U58/CCU922830-05). The contents of this summary are solely the responsibility of the authors and do not necessarily represent the official views of the CDC.

CALIBRATION

A calibration session was held for fourth year dental students at the UNLV SDM using a calibration PowerPoint® created by a UNLV SDM staff member. The UNLV SDM requested the calibration session be done by PowerPoint® during a regularly scheduled class session rather than calibrating using the special needs population due to logistics. The Disabilities and Oral Health Workgroup agreed to this arrangement. The calibration was held in September 2007 just prior to the first screenings. (Appendix A)

PROCESS

In April 2007, the OHSC and the OHB were asked to attend a meeting of the Disabilities and Oral Health Workgroup. Key factors related to the BSS were discussed. Topics included: facilities that would participate in the screening, what data would be collected, who would perform the screenings, Institutional Review Board (IRB) approval, necessary forms, referral process for participants in need of dental treatment, primary contacts at screening locations, screening supplies, and calibration.

The two facilities that would participate were both located in Las Vegas. DRC is the State of Nevada operated regional center in the Las Vegas area, serving Clark, and parts of Lincoln and Nye counties. The facility supports people with developmental disabilities in their efforts to live, work and recreate in the community. Support services are available for approximately 1,000 off campus clients and 54 on campus residential clients. The Rawson-Neal Psychiatric Hospital (RNPH) is part of Southern Nevada Adult Mental Health Services, also an entity of the State, and provides short-term inpatient psychiatric treatment to approximately 190 patients. The maximum stay for these patients is 21 days.

Staff from the UNLV SDM volunteered fourth year dental students to carry out the screenings under the supervision of faculty members who are licensed dentists. It was agreed the screenings would take place during the fall semester. Based on prior screening experience it was estimated that it would take approximately fifteen minutes per client and each dental student would see four clients per hour. The number of clients projected to participate was 1,200 which equated to 300 hours of screening time.

The next step was to schedule a meeting at the two sites chosen to participate in the BSS. Meetings were held at both sites in May 2007. The DRC staff chose a location on their campus for their clients to be screened, suggested Saturdays as the preferred day for screening, provided input on liability, demographic and screening forms, and agreed to review draft copies of these forms with feedback no later than May 30, 2007. The meeting at RNPH was more problematic as the facility was undergoing multiple changes in staff. At this point they had not officially agreed to participate in the BSS. The interim Director of Nursing (DON) at RNPH advised the OHSC and OHB that each patient's psychiatrist would need to determine if the patient would be able to participate in an oral health screening. Another challenge would be the fact that the average stay at the facility is only 21 days.

The acting Medical Director at RNPH contacted the OHSC at the end of May and asked if the screenings could be postponed until spring 2008 due to the facility not having a Medical Director or DON. Concern was also expressed about the amount of work that would be required of RNPH nursing staff. Patients being screened would need to be escorted to and from the screening area and this would require nursing staff to work overtime.

By the beginning of June 2007 things were beginning to come together. The staff from UNLV SDM and DRC had approved a final format for the necessary forms and RNPH had appointed a new DON. The interim Medical Director at RNPH agreed to have approximately 40 clients participate in the screenings. The OHSC met with the new DON at RNPH during her first week in the position. The DON had many questions pertaining to protocol to be followed during the screenings. She emphasized it would be important dental students follow strict guidelines pertaining to dress code and tracking of materials brought into and removed from the facility.

The IRB application was due the end of June 2007. Approval was necessary from the UNLV IRB in order for the dental students and faculty to participate as well as to gain access for screening of clients at DRC and RNPH. The IRB application was very detailed and required a significant amount of collaboration between the OHSC and a UNLV SDM staff member. The IRB packet included all of the forms to be used during the BSS. (Appendix B)

A conference call was held in late June 2007 between representatives of the OHP staff, UNLV SDM staff, RNPH staff, DRC staff, and a member of the Governor's Commission on Mental Health and Developmental Services, to discuss the IRB submission and other technical aspects of the BSS. During this meeting it was clarified that the number of clients to be screened at RNPH would be 50. Both RNPH and DRC agreed to provide an orientation session at the UNLV SDM prior to the dental students beginning the screenings. It was during this meeting the referral process began to be discussed for RNPH patients. The DON at RNPH was concerned about how patients would receive care if they were found to be in need of dental treatment. The only form of transportation available for RNPH patients found to be in need of dental treatment would be via ambulance to University Medical Center. It was recommended that any non-acute treatment be postponed until the patient was released from RNPH, as transportation via ambulance would not be cost effective.

On June 26, 2007 the IRB packet was submitted for the July 24th IRB meeting.

The OHP had agreed to provide the following screening materials: flashlights and batteries, mouth mirrors, cotton tipped applicators, mouth props, facemasks, non-latex gloves, hand sanitizer, anti-bacterial wipes, paper towels, trash bags, toothbrushes, and all necessary forms. These items were shipped to the UNLV SDM in boxes for transport to DRC and RNPH screening sites. A tracking list was completed each time materials were shipped/ordered for screenings. (Appendix C) The OHSC created a sign-up sheet for the

dental students to indicate what size glove they would need. (Appendix D) Once the sheet was completed by the dental students, the OHSC then designated a specific color for each size of glove indicated to help determine how many gloves needed to be ordered based on the expected number of people to be screened.

The OHSC contacted DRC and RNPH to find out what time their clients/patients and staff took lunch so a schedule could be created. The OHSC then created the client/patient schedule for DRC and RNPH. (Appendix E) The schedule allowed for twenty minutes per client. The increase in time allotted per person took into account the fact that the clients/patients needed to be transported to and from the screening area. The dental student teams were told to arrive 20 to 30 minutes ahead of time to allow for setup of the screening area and to verify Consent Forms were completed and signed.

Early in July the OHSC was contacted by the DON from RNPH regarding several concerns about the screenings. Her concerns included follow-up for patients in need of dental treatment or who had a suspicious lesion, transportation, and the cost of treatment liability. The OHSC discussed these concerns with a member of the Governor's Commission on Mental Health and Developmental Services, who had been involved with the project from the beginning, who then offered to contact the Commission's legal counsel for further advice.

The IRB decided to change the IRB from a full review to an exempt review since the research was part of the UNLV SDM curriculum. The Board wanted the Assent and Consent Forms to be reworded and submitted with the Exempt Research Form. The IRB also required a Facility Affiliation Agreement be completed by DRC and RNPH. (Appendix F) The legal counsel for RNPH decided during this time they would require a Competency Form to be completed by a staff psychiatrist prior to a patient being screened. (Appendix G)

The IRB came back again requesting revisions to some of the forms and requiring facility staff that would be assisting clients/patients with the completion of the Consent Form to complete a course on informed consent. (Appendix H) (https://www.citiprogram.org/members/learners/modulepreview.asp?intModuleID=3) On August 23, 2007 the final IRB Exempt Research Form along with the necessary screening forms were submitted to the IRB. (Appendix I) Time was of the essence given that the first screenings were scheduled to take place at DRC on Saturday, September 22, 2007 and the necessary forms did not have the IRB stamp. Included in the forms needing to be approved were the Consent Forms that needed to be distributed to DRC in order for staff to distribute them to their clients prior to the first screenings. The forms were finally approved and given the IRB's official stamp on September 10, 2007. (Appendix J)

While waiting for the IRB to approve the Exempt Research Form the OHSC scheduled meetings at DRC, RNPH and UNLV SDM to discuss further details related to the screenings. DRC agreed to handle transportation of their off campus clients and requested those clients be screened first with on campus clients being used to fill no

shows and cancellations. The Saturdays scheduled for the screenings were confirmed with all partners involved.

The meeting at UNLV SDM was primarily to discuss the flow of all of the forms and who would be overseeing the security of the forms. It was decided in order to keep the identity of those screened anonymous, screening forms would be numbered. The forms submitted by DRC and RNPH for each client/patient would receive the corresponding number. The client/patient name would be placed on a "key" along with the corresponding number. A UNLV SDM staff member would be the only person with access to the "key." The "key" and all forms with identifying information would be kept in a locked space at UNLV SDM. The OHB created flow sheets outlining how forms would be processed during screenings. (Appendix K)

The initial screenings took place at DRC on Saturday, September 22, 2007. The first two Saturdays had very limited participation. Upon contacting DRC about the lack of participation the OHSC was informed the Public Guardian had advised DRC clients not to complete the Consent Forms. It was finally agreed upon that DRC clients could participate in the screening; however they had to be given the option of not having their screening results included in the data collection. The five following screening dates saw an increase in the number of clients screened. In the end, 116 DRC clients out of a possible 1,054 were screened.

Two Saturdays were scheduled for screening at RNPH. These screenings had a higher participation rate with 41 out of a possible 50 being screened.

The dental student teams consisted of one screener, a fourth year student, and one recorder, typically a third year student, who were assigned to a portable dental chair for screening. During the screenings the dental student teams were accompanied by UNLV SDM faculty. The faculty member assigned to the teams made sure screening materials arrived at the site and assured that all screening paperwork was secure. The OHSC kept in contact with DRC and RNPH to confirm the sites were ready for the dental student teams.

Following completion of the screenings in December 2007 the OHSC, OHB, and Oral Health Program Evaluation Specialist held meetings at DRC, RNPH, and UNLV SDM to get feedback about their experiences as participating partners in this project. The results of these meetings are included at the end of this process report. (Appendix L)

SUMMARY

The screenings took place on seven Saturdays from September to December 2007, with holiday weekends being excluded. During planning meetings held prior to the start of the screenings, DRC indicated Saturday as the preferred day for screening; however feedback after the screenings were complete indicated their clients would have preferred the screenings not be held on Saturdays as the clients had other activities planned on those days. This was one of the reasons indicated for lack of participation at DRC.

The collaboration with the UNLV SDM made the completion of this project possible. It was a win-win for UNLV SDM and the OHP. UNLV SDM students were asked to volunteer for screenings on Saturdays as part of the *Community Outreach: Disabled and Special Needs Population* course and the OHP reduced the expenses associated with this type of screening. It is difficult to determine the actual cost per person screened since many of the supplies were on hand from previous screening projects. Overall costs were reduced due to the fact OHP staff did not incur as many travel expenses since their primary function was to be in an advisory capacity versus collecting the data themselves as has been the case in several previous BSS projects.

Some dental students did express dissatisfaction with the screening schedule at DRC. The dental students were asked to commit to setting aside a Saturday several weeks in advance. When the schedule at DRC had to be revised at the last minute due to lack of client participation, some dental students mentioned to UNLV SDM staff they not only had to give up a Saturday in advance they also had to find another volunteer activity to satisfy their course requirement. Those students who did participate in the screenings at DRC seemed to generally have a positive experience.

As has occurred in previous BSS projects the turnover of staff at the facilities chosen for the screening added to the challenge of coordinating the project. When turnover occurs the new staff must be brought up to speed on the screening. Many times this results in a different point of view and different expectations regarding the project.

After the first screening date at RNPH the DON contacted the OHSC about two patients whose Treatment Urgency Form indicated they were in need of Urgent Treatment. Although referral for treatment had been discussed during the planning of the BSS the issue of patients at RNPH needing urgent treatment had not been completely resolved by the time the screenings began. RNPH could not allow patients out of the facility for dental treatment unless the patient was transported to University Medical Center (UMC) via ambulance. The DON was very concerned about the expense RNPH would incur for this treatment as well as the amount of time the patient would have to wait at UMC's emergency room. This situation did not have a resolution and fortunately no other patients at RNPH were found to be in need of urgent treatment.

RECOMMENDATIONS

The following recommendations are included for future consideration in the interest of improving the screening.

1. Contact the Public Guardian in advance to discuss details of the screening and get their approval.

2. Provide Consent Forms to the facilities early so they can contact the families to discuss the screening thoroughly.

3. Apply to the Institutional Review Board (IRB) further in advance to eliminate sending out Consent Forms at the last minute.

4. Have an in-depth discussion about transportation needs.

5. Make sure both the facility and those facilitating the screening completely understand the referral mechanism for clients found to be in need of treatment.

Desert Regional Center Oral Health Screening Survey Calibration

R. Michael Sanders, DMD, EdM

September 19, 2007

Desert Regional Center Oral Health Screening Survey

- This is a screening – NOT a thorough dental examination.
- You are not diagnosing dental disease.
- The information collected will be used as an indicator of the patient's oral health and as a statewide comparison for future program planning.

Screening Site Protocol

- Arrive 30 minutes early
- Check in at the office first – you will be escorted to the screening room
- Wear scrubs and your white coat
- Do not wear jewelry – particularly something that dangles
- Each screening is allocated 20 minutes
- Note patient's ID on the Treatment Urgency Form

The Chairside Team

- One screener & one recorder
- Screener examines
- Recorder asks the questions on the Oral Health Screening Form

Verbal Instruction/Permission Script
(Child or reading challenged adult)

Hello. My name is _____. I will be looking in your mouth today to see if your teeth have any cavities. I will be using a small mirror that goes in your mouth to look at your teeth. You will lie back in the chair and put on these colored glasses. (Show the patient the glasses.) I will turn on a light to help me look in your mouth. It will not hurt and will only take a few minutes. All you have to do is hold your mouth open. If you have a problem holding your mouth open while I look in it, I can put this (Show the patient the mouth prop.) between your teeth to help you. It doesn't hurt and may make it easier for you to do this. (Give them the name of your partner) _____ is here to help us. He/she will be asking some things that I will answer. These are things I need to know about your mouth and teeth. I will also put my fingers in your mouth to feel the inside of your cheeks. This will not hurt. I will ask you to stick your tongue out so that I can look at it. When you stick your tongue out I will put some gauze on your tongue. (Show the patient the gauze.) I will hold your tongue so that I can look at it. This may feel funny, but it will not hurt. Please tell me if you do not like what I am doing and I will stop. Thank you for helping me. You are a very good helper.

The Screening

- **KISS: Keep It Simple, Screeners!**
- **Follow the Oral Health Screening Form questions in order**
- **Take what the patient will give!**
- **Resist the urge to over diagnose**
- **Review screening packet ahead of time**
- **Organization is a time saver!**

What Are We Looking For?

- **Oral Questions:**
  - **OHI habits**
  - **Any pain**
  - **Permission to examine**
- **Clinical Exam**
  - **Edentulous**
  - **Caries / Caries experience**
  - **Missing teeth**
  - **Tissue inflammation**
  - **Calculus**
  - **Soft tissue lesions**

Is it Caries?

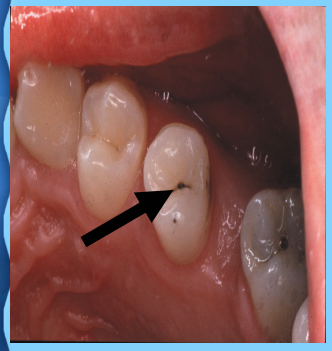
- **Loss of ½ mm or more of tooth structure**
- **Dark gold to dark brown coloration of the walls of the cavity**
- **Retained root**
- **Existing filling with new decay**

- **YES**

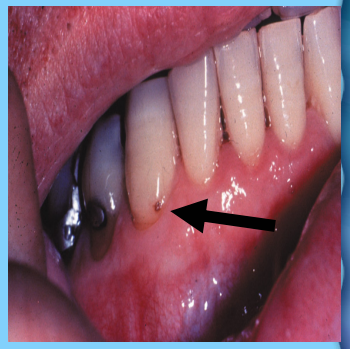
Is it Caries?

- Be Conservative – "When in doubt, rule it out!"
- Stained grooves & pits are not caries
- Halos count only if there is a ½ mm loss of tooth structure

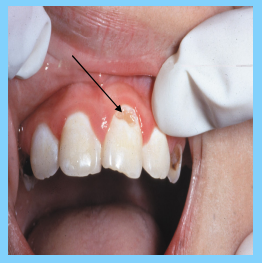
Threshold pit & fissure cavity



Threshold smooth surface cavity

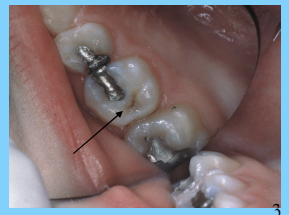


How would you record these?



1

2



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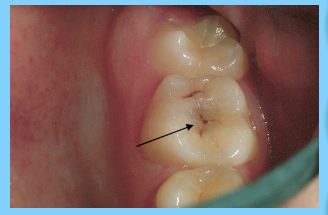


4

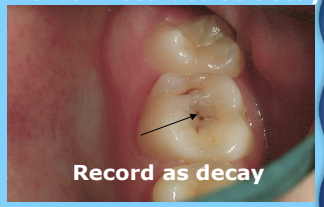
How would you record these?

Record as decay

Chipped, not obvious decay
Record as FILLED

Decalcification
is NOT recorded as decay

Record as decayed
& filled



Record as decay

Treatment Urgency:

- ❑No Obvious Problem/Needs Routine Preventive Care
- ❑Needs Restorative (Treatment) Care
- ❑Urgent Care (Pain or Swelling Present)
- ❑Suspicious soft tissue area

Infection Control

- **Obvious - change gloves between patients.**
- **If a gloved hand has touched the mucous membranes, lips, or saliva, gloves must be removed and hand sanitizer used prior to putting on a new pair of gloves.**
- **Disinfectant wipes and paper towels will be included in your supplies.**
- **It is recommended that both the screener and recorder wear a mask.**
- **The recorder should also adhere to hand washing protocol.**

Remember….

- **Smile!**
- **Enjoy the patients.**
- **Take what they give you.**
- **What you are doing is important!**

UNLV
UNIVERSITY OF NEVADA LAS VEGAS
Office for the Protection of Research Subjects

IRB Received Date Stamp—Office Use Only	IRB Protocol Number—Office Use Only

Research Protocol Proposal Form
for Research Involving Human Subjects

Evidence of CITI certification (www.citiprogram.org) must be submitted with this protocol proposal form.

Instructions:

1. Complete all sections of this form. Do not reference other sections as a response (i.e. "see section…" or "see attached…")
2. Obtain all necessary signatures.
3. Submit one complete protocol package with all enclosures. You will be notified if additional copies are necessary.
4. Projects with funding/proposed funding must include copy of the application or proposal.

Note:

1. Handwritten forms **will not** be accepted.
2. INCOMPLETE FORMS WILL BE RETURNED.
3. For your records, it is important that you keep a copy of this completed form.

1. Submittal Date: 6/26/2007

2. Duration of Study

Anticipated Start Date: 9/17/2007
Anticipated Termination Date: 5/03/2008

NOTE: Research Studies may not begin until you have received notification of IRB approval. All research proposals are approved for a maximum of 1 year and can be re-reviewed at any time within that year at the discretion of the IRB.

3. Research Protocol Title (Research Protocol Title must match the funding/proposed funding application or proposal):
Governor's Commission Oral Health Screening on Special Needs Population

4. Investigator(s) Contact Information

(One person must be designated as the PI. The PI must be a UNLV faculty or professional staff member in all cases involving studies carried out by students or fellows.)

A. Principal Investigator (*Name and Credentials*): Mildred A. McClain, PhD

☒ Faculty ☐ Faculty Advisor ☐ Professional Staff

School/College/Center: School of Dental Medicine
Department: Professional Studies Mail Stop: 7410
Mailing Address: 1001 Shadow Lane, Las Vegas, NV 89106-4124
Phone Number: (702) 774-2642 Fax Number: (702) 774-2721
E-Mail Address: millie.mcclain@unlv.edu

B. Student/Fellow Investigator (*Name and Credentials*): _____

☐ Undergraduate ☐ Master ☐ Doctorate ☐ Fellow

School/College/Center: _____
Department: _____ Mail Stop: _____

Mailing Address: _____

Phone Number: _____ Fax Number: _____

E-Mail Address: _____

NOTE: All student/fellow initiated research must be submitted as an independent project with the Faculty Advisor listed as the Principal Investigator. The Faculty Advisor must sign the Faculty Advisor Assurance statement in Section 27B. The Student/Fellow Investigator must sign the Student/Fellow Investigator Assurance statement in Section 27C.

C. PLEASE COMPLETE ONLY IF APPLICABLE

Co-Principal Investigator *(Name and Credentials):* R. Michael Sanders, DMD, EdM

☒ Faculty ☐ Professional Staff

School/College/Center: School of Dental Medicine

Department: Clinical Sciences Mail Stop: 7410

Mailing Address: 1001 Shadow Lane Campus

Phone Number: (702) 774-2660 Fax Number: (702) 774-2721

E-Mail Address: michael.sanders@unlv.edu

5. Research Team Members: List all research team members who will be involved in this research project. Research team members are persons who have direct contact with subjects, contribute to the research in a substantive way, have contact with subjects' identifiable data or biological samples, or use subjects' personal information. (For additional guidance, refer to the sample form on the OPRS website.)

NAME and DEPARTMENT	ROLE IN PROTOCOL	ROLE IN CONSENT PROCESS	SPECIFIC EXPERIENCE WITH ROLE IN PROTOCOL
Mildred A. McClain, PhD, Professional Studies	Principal Investigator	Inservice to site staff regarding consent process	Prior research.
R. Michael Sanders, DMD, EdM, Clinical Sciences	Co-Principal Investigator	Inservice to site staff regarding consent process	SDM faculty licensed dentist
SDM Clinical Faculty, Clinical Sciences Department: Dr. Francis Curd Dr. Kenneth Duffie Dr. Wendy Woodall Dr. Michael Sanders Dr. Bernard Hurlbut Dr. Richard Walker Dr. Charles (Ned) Hill Dr. Monique Phillips Dr. Raymond Tozzi	Supervising third and fourth year student dental doctors conducting oral health and soft tissue screenings.	None	SDM faculty licensed dentist
SDM third and fourth year student dental doctors, Professional Studies Department	Performing oral health screenings under the supervison of licensed dental faculty	None	Will be performing oral health screening under the supervision of SDM faculty licensed dentists. All students have CITI Certification as a requirement of their first year curriculum in dental school.
Marcia Ditmyer, PhD, CHES	UNLV SDM Bio-statistician	None	Statistical Analysis
Jim Jordan	Nevada State Health Division - Oral Health Program Bio-statistician	None	Statistical Analysis

6. Project Site(s) (Check all boxes indicating where the study is conducted.)

☐ University of Nevada, Las Vegas (UNLV)
- ☐ Maryland Campus (main)
- ☐ Paradise Campus
- ☐ Shadow Lane Campus
- ☐ UNLV leased property. Explain:

☒ Other: (Specify and Explain): Desert Regional Center, 1391 South Jones Blvd., Las Vegas, NV 89146-1200 and Rawson-Neal Psychiatric Hospital, 6161 W. Charleston Blvd., Las Vegas, NV 89146-1200

NOTE: If the project site is other than UNLV, Facility Authorization Letter must be submitted.

7. Research Terms

Provide up to three terms, keywords, or short phrases that describes the research to be performed using the guidelines below:

1. Research area (biomedical, social behavioral): biomedical.
2. Study topic area (e.g., physical therapy, psychology): dentistry
3. Subject class (e.g., healthy adults, prisoners): special needs population

8. Proposal Summary

Summarize the proposed research project. The summary should be written in non-technical language that can be understood by non-scientific individuals. The summary must not exceed 200 words.

8.1 A brief statement of the research question (hypothesis) and related theory supporting the reason for the study.

The special needs population will have a higher incidence of caries experience and access to care issues than the general population.

8.2 A brief description of the procedure(s) involving human subjects.

Participants or their legally authorized representative will be asked to complete a demographic questionnaire (attachment 1) pertaining to their oral health, allow a third and/or fourth-year student dental doctor, supervised by a UNLV School of Dental Medicine licensed faculty dentist, to perform an oral health screening. This is NOT a full dental examination. Each tooth will not be completely evaluated and dental radiographs (X-rays) will not be taken. The oral health screening is not meant to take the place of a complete dental examination. Screening indices on the oral health screening form (attachment 2) will be recorded for analysis of caries indices and access to care. These screenings will result in advising client of need for treatment urgency (attachment 3).

PLEASE NOTE: Complete description of the study procedure(s) must be specified in Section 26.

9. Number of Research Subjects

Total number of subjects: 800 to 900

10. Research Subject Classification

10.1 Check all applicable boxes

- ☐ UNLV Students (general student body)
- ☐ Student Subject Pool (Dept.):_____
- ☐ Healthy Adults - Age range: _____
- ☐ Minors (under age 18) - Age range: _____
- ☐ Clark County School District Students
- ☒ Cognitively or Psychologically Impaired (See consent form guidelines)
- ☐ Elderly Subjects
- ☐ Prisoners or Parolees
- ☐ Healthy Control Group
- ☐ Pregnant Women
- ☐ UNLV Employees
- ☒ Institutionalized Residents

☐ Non-English Speaking (Include consents in the appropriate language) ☒ Other - Describe: Special needs.

10.2 Summarize the inclusion and exclusion criteria that must be met in order for a person to participate in the study.

Inclusion: Only clients of Rawson-Neal Psychiatric Hospital and Desert Regional Center in Las Vegas, Nevada, who have returned signed consent forms.

Exclusion: Those clients who do not have signed consent forms.

10.3 What is the gender of subjects? ☐ Male ☐ Female ☒ Both

10.4 Are there any enrollment restrictions based on gender, pregnancy or childbearing potential? ☐ Yes ☒ No

If yes, please explain the nature of the restriction(s) and provide justification.

_____

10.5 Are there any enrollment restrictions based on race or ethnic origins? ☐ Yes ☒ No

If yes, please explain the nature of the restriction(s) and provide justification.

_____

11. Purpose of Study

The purpose of this screening is to evaluate the oral health of the special needs population.

12. Privacy and Confidentiality

Privacy *refers to a person's desire to control the access of others to themselves. Privacy concerns people.*

Confidentiality *refers to the researcher's agreement with the subject about how the subject's identifiable private information will be handled, managed, and disseminated. Confidentiality concerns data.*

12.1 What are the methods used to ensure confidentiality of participation and data obtained?
All information gathered in this screening will be numerically coded and kept completely confidential. All consented subjects will be assigned a random coded identifier by the Nevada State Health Division Oraql Health Program statistician (Jim Jordan). This number will be used to document all data for reporting to the Governor's Commission on Mental Health and Developmental Services and application for oral health disparities grants.

12.2 What safeguards are used to protect against identifying, directly or indirectly, the subject involved in the study? No reference will be made in written or oral materials produced by the study that could link the subject to this screening.

12.3 What safeguards are used to protect the information from disclosure?
All records will be stored in a locked cabinet in Building B, room 243, at the UNLV SDM for 3 years post completion of the screening after which Dr. McClain will monitor shredding of all information.

12.4 What provisions exist for controls over access to data?
No one other than the Nevada State Health Division Oral Health Bio-statistician (Jim Jordan) and the UNLV SDM Professional Studies Bio-statisitician (Dr. Marcia Ditmyer) will be allowed access to the data.

12.5 Are subjects asked to fill out any materials that are shared with other groups (e.g. voluntary health organizations, advocacy groups) that provide identifiers? ☐ Yes ☒ No
If yes, describe: _____

12.6 Will the subjects' data be coded? ☒ Yes ☐ No
If yes, how? Numerically

12.7 Will data generated be used for purposes other than this research project? ☒ Yes ☐ No
If yes, how? Data generated from the screenings will be used for reporting to the Governor's Commission on Mental Health and Developmental Services and application for oral health disparities grants.

12.8 Where will the data be stored? *(For review/audit purposes, records must be stored on UNLV property.)* All records will be stored in a locked cabinet in Building B room 243 at the UNLV SDM.

12.9 How long will the data be stored? *45CFR46.115(b)- Records relating to research which is conducted shall be retained for at least 3 years after completion of the research.* 3 years

12.10 What are the plans for the final disposition or destruction of the data? Shredding of all material will be completed under the supervison of Dr. McClain.

13. Recruitment Procedures

13.1 Describe below the processes used for selecting subjects and the methods of recruitment, including use of letters and/or advertising. Include, when, how and by whom the subjects will be recruited. Do not include inclusion and exclusion criteria which were already listed in Section 10.2.
Several weeks prior to the screening, subjects will be recruited by employees of the Rawson-Neal Psychiatric Hospital and Desert Regional Center in Las Vegas, Nevada. Consent forms will be distributed by the employees of the Rawson-Neal Psychiatric Hospital and Desert Regional Center. Clients of Rawson-Neal Psychiatric Hospital and Desert Regional Center will be given information on the availability of free oral health screenings that will be conducted at their respective facilities.

13.2 Will subjects be recruited from one or more schools, community centers, organizations, trade groups etc.? ☒ Yes ☐ No
If yes, please specify the source(s): Rawson-Neal Psychiatric Hospital and Desert Regional Center.

NOTE: Provide a Facility Authorization Letter from the performance site facility giving the PI permission to perform the study at that site.

13.3 Indicate the types of recruitment materials to be used below (check all that apply). Attach copies of all recruitment materials to this application.

☐ Advertisements ☐ Newsletters ☐ Internet
☐ Brochures ☐ Radio ☐ Contact letters (Physician Letters, Teacher Letters)
☐ Flyers/Posters ☐ Television ☐ Other (Describe) _____

☒ This research study will not be using any of the above information.

13.4 Will subjects be recruited from a non-public registry? ☐ Yes ☒ No

If yes, specify the source: _____

NOTE: Provide a letter from the director of the registry authorizing your access to the identifiable data for the purpose of this study. The letter needs to clearly describe how access to the identifiable information is ethically possible, (i.e. it confirms that subjects have given permission for contact and authorized the distribution of their names and address).

13.5 Are you studying pre-existing data? (e.g. academic records, medical records or specimens) ☐ Yes ☒ No

If yes, specify the source: _____

13.6 Do you or any member of the research team have an authoritative role (i.e. Instructor, Counselor, etc.) over the research subjects? ☐ Yes ☒ No

If yes, please explain: _____

14. Research Activities (Part A)

Please check any/all that apply to the proposed research study.

☒ Collection of data is through **non-invasive procedures** routinely employed in clinical settings, excluding x-rays or microwaves (e.g., physical sensors that do not shock or invade the subject's privacy, weighing or testing sensory acuity, magnetic resonance imaging, EEG, EKG, moderate exercise or strength testing with healthy non-pregnant subjects).

☐ Collection of data involves review of data, documents, records or specimens that were originally collected for non-research purposes (e.g., medical records).

- ☐ Existing human biological specimens will be used.*
- ☐ Prospectively collected human biological specimens will be used. **

  Indicate source and dates when the data were collected: _____

  * Specimens must be "on the shelf" at the time of the submission of the application.

  ** Specimens will be collected after the study has started.

☐ Collection of data is from audio or visual recordings.

☐ Research activities involve observing individual or group characteristics when considering the subject's own behavior (including perception, cognition, motivation, identity, language, communication, socio-cultural beliefs, practices or behavior).

☒ Research employing survey, interview, oral history, focus group or program evaluation measures for purposes of research.

☐ Research activities involve medical devices that have been approved for marketing and are used as prescribed.

Identify device(s): _____

☐ Blood samples are collected by finger stick or venipuncture only from non-pregnant healthy adults in amounts less than 550 ml in an eight-week period and no more than twice per week.

Provide a brief description of blood collection methods._____

☐ Prospective collection of biological specimens by non-invasive means (e.g., hair and nail clippings, extracted teeth, excreta and external secretions, uncannulated saliva, placenta removed at delivery, amniotic fluid obtained at rupture of membrane prior to or during delivery, dental plaque and calculus, mucosal and skin cells collected by swab and sputum collected after saline mist nebulization).

☐ None of the above categories apply to the proposed research study.

15. Research Activities (Part B)

15.1 Please check any/all that apply to the proposed research study

☐ False or misleading information to subjects (deceptive studies)

☐ Procedures for debriefing subjects: _____

☐ Invasive biomedical procedures

Explain procedure: _____

Are provisions for medical care necessary?

- ☐ Yes, please explain: _____
- ☐ No, please explain: _____

Has a qualified UNLV Faculty Member participated in planning the study?

☐ Yes, please identify by name and qualifying credential: _____
☐ No

Will the study involve drugs, radiation, lasers, high-intensity sound, etc.?
☐ Yes, please identify: _____
☐ No

☐ Sensitive questions will be asked about personal issues

☐ The study involves use of potentially hazardous materials (Explain): _____

☐ The research includes collection/storage of data/biological specimens for future research analysis. If yes, the consent document must address the possibility of future use.

☐ Procedures are novel or not accepted practice (if this category applies, explain in the Informed Consent Form how provisions are made to correct, treat or manage unexpected adverse effects)

☐ Risky procedures or harmful effects, including discomfort, risk of injury, invasive procedures, vulnerability to harassment, invasion of privacy, controversial information or information creating legal vulnerability (if this category applies, explain in the *Informed Consent Forms* how harmful effects will be addressed and how benefits outweigh risks)

☒ None of the above categories apply to the proposed research study.

15.2 Dissemination and Storage of Research Information

Will the results of the research study be provided to the research subject? ☐ Yes ☒ No
If yes, please explain: _____

15.3 Quantitative Design Elements (if applicable)

Describe the statistical procedures that will be used and specify the following:

Statistical design: Sample of convenience
Dependent variables: Age; gender; race; ethnicity; institution of care
Independent variables: Caries experience; access to care

16. Medical Devices

16.1 Are you using a medical device? ☐ Yes ☒ No
If no, then continue to section 17. If yes, please complete the answers below.

16.2 Is this a **SIGNIFICANT RISK** (SR) or **NON-SIGNIFICANT RISK** (NSR) device?
☐ SR ☐ NSR

16.3 Is this an **INVESTIGATIONAL MEDICAL DEVICE** ☐ Yes ☐ No

APPROVED MEDICAL DEVICE FOR AN **UNAPPROVED USE.** ☐ Yes ☐ No
If yes, indicate DEVICE name: _____
IDE number: _____
Sponsor/Manufacturer: _____
NOTE: Please provide the investigator's brochure when using an investigational device.

FDA **APPROVED** MEDICAL DEVICE FOR AN **APPROVED** USE: ☐ Yes ☐ No
If yes, indicate DEVICE name: _____
Sponsor/Manufacturer: _____
NOTE: Please provide the package insert when using an approved device.

16.4 Is the IDE (Investigational Device Exemption) held by the sponsor or by the investigator?

☐ Sponsor (Please forward copies of the annual report from the sponsor to the IRB.)
☐ Investigator (Please provide a copy of the original IDE application and copies of the annual reports at the time of periodic review)

17. Risks

17.1 Summarize the nature and amount of risk (including side effects) or substantial stress or discomfort involved. This oral health screening includes only minimal risks and may cause discomfort with answering questions or having someone complete an oral health screening and soft tissue exam.

17.2 What are the potential risks/discomforts associated with each intervention or research procedure? Participant may become uncomfortable with answering questions or having someone complete an oral health screening exam.

17.3 Estimate the probability (i.e. not likely, likely, highly likely, etc.) that a given harm will occur, its severity, and its potential reversibility. not likely.

17.4 What procedure(s) will be utilized to prevent/minimize any potential risks or discomfort? Examples of risk include physical risks, psychological risks (such as substantial stress, discomfort, or invasion of privacy) and social risks (such as jeopardy to insurability or employability). Mouth props (attachment 4), devices used to hold the mouth in an open position, will be used at the descretion of the screener to reduce the possibility of the screener being bitten. Subjects may also feel uncomfortable with screeners conducting the oral health and soft tissue screenings.

17.5 What is the overall risk classification of the research?
☒ Minimal ☐ Greater than minimal ☐ Significant
☐ If unknown, please explain: _____

18. Benefits

18.1 Describe the probable benefits of the research for the individual subject(s).
a

18.2 Describe the probable benefits of the knowledge gained for society. Societal benefits generally refer to the advancement of scientific knowledge and/or possible benefit to future subjects.
We hope to learn the oral health status of the mentally disabled and special needs population in order to report the findings to the Governor's Commission on Mental Health and Developmental Services to respond to the access to care goals addressed in Healthy People 2010 objectives for the Nation.

19. Risk-Benefit Ratio (Explain how the potential benefits of the research outweigh the potential risks and how these risks are justified.)
This oral health screening includes only minimal risks in that the client may become uncomfortable with answering questions or having someone complete an oral health and soft tissue screening. Oral health screening will identify possible caries which will result in advising the subjects with treatment urgency.

20. Cost to Subjects (Do not include financial costs in this section. See Section 22.)

20.1 Briefly describe the activity (i.e. laboratory testing, survey completion, travel time) that involves participation time: The actual oral health screening will take approximately 5 minutes.

20.2 Amount of participation time: 15 to 20 minutes per day for 1 day(s)

20.3 Describe any additional costs: none

21. Project Funding

21.1 Funding Status: ☐ Funded ☐ Pending ☒ None (go to section 22)
Note: If funded/pending funding, please submit a copy of the application or proposal.

21.2 Funding Source:
☐ Federal/State
☐ NIH ☐ NSF ☐ NASA ☐ BRIN ☐ DOE ☐ Other:_____
☐ UNLV Internal Grants
☐ SITE ☐ NIA ☐ URA ☐ ARI ☐ Other:_____
☐ Other: _____
☐ Self-funded

21.3 Are there any other contributions or support (e.g. device, drugs, etc.) provided by a company/sponsor/granting agency?
☐ Yes ☐ No If yes, explain: _____

21.4 Is any other type of contribution (aside from devices or monetary funds) being made by a company/sponsor/granting agency?
☐ Yes ☐ No If yes, explain: _____

21.5 Has this project been submitted to the Office of Sponsored Projects (OSP)?
☐ Yes ☐ No Submission date: _____
If no, explain: _____

21.6 Sponsor: _____ Contract or Grant Number: _____

22. Financial Information *(For additional guidance, refer to the sample form on the OPRS website.)*

22.1 What are the financial costs involved as a result of participation in the research study. None

22.2 Are there additional expenses for the subject related to this protocol? ☐ Yes ☒ No

If yes, please describe. _____

22.3 Will subjects be paid or otherwise compensated for research participation? ☐ Yes ☒ No

If yes, please respond to the following questions:

a) Describe the nature of any compensation to subjects. Include cash, gifts, travel reimbursements, etc. _____

b) Provide a dollar amount, if applicable, and indicate method of payment. _____
☐ Cash ☐ Check ☐ Other: _____

c) When and how is the compensation provided to the subject? _____

d) Schedule of payments: _____

23. Consent

Refer to the UNLV Informed Consent Template to ensure that your submission follows the current standard consent format.
Attach a copy of all consent form(s) and/or informational letter(s) used to describe the research study to potential subjects.
Note: Consent must be obtained from subjects prior to enrollment/participating in the research study.

23.1 Describe the consent process for enrolling subjects into this study. Only those subjects from the Rawson-Neal Psychiatric Hospital and the Desert Regional Center that have returned a signed consent form(s) will be allowed to participate in the oral health screening (attachment 5: Informed Consent; attachment 6: Youth Assent/Agreement;

Attachment 7: Parent Permisson. Informed Consent - for adults (subjects 18 yrs of age and older); Youth Assent - for subjects 12 to 17 year olds; and Parental Permission - for subjects under 18 years of age.

23.2 Where will the consenting process take place? At each individual facility.

23.3 Will there be an opportunity for the subject to take the consent form home to discuss their participation?

☐ Yes ☒ No If no, explain why. There will be a verbal script (attachment 8) for those subjects under age 12 and for subjects with comprehension incapabilities. Informed consent will be explained to subjects, parents and/or their legally authorized representative by the site staff at each facility since subjects are residents of the facilities. The site staff person who explains the screening and consent process will also sign the consent form acknowledging that they have explained the consent form and the oral health screening examination to the client.

23.4 What method(s) will be used to educate and increase the potential research subjects' knowledge of the research project and their rights as a subject? Prior to the oral health screening, there will be an in-service for facility site staff explaining the research subjects rights (attachment 9) and the oral health screening . This in-service will be conducted by the SDM research team.

23.5 What method(s) will be used to evaluate the understanding of the potential research subject's comprehension about the research project and their rights as a subject? *(Check all that apply)*

☐ Verbal feedback of information

☐ Pre and Post-test

☒ Other (describe): Facility site staff will co-sign the Informed Consent Form (attachment 5) indicating that they have explained the screening protocol to the subject and that the subject understands the screening procedure.

23.6 Please list all Consent Forms *(Please compose all consent forms in a language appropriate to the study population.)*

Title of Consent Form	Purpose
1.UNLV Informed Consent	To ensure that the subjects are informed of the purpose of the oral health screening and who will be conducting the screening.
2.UNLV Youth Assent	To ensure that the subjects also consent to the oral health screening.
3.UNLV Parental Permission	To ensure that parents of youth under the age of 18 have consented to the oral health screening.
4._____	_____

23.7 Debriefing: If the study includes a debriefing script or information given to subjects, please attach with the submission.

Is a debriefing script necessary? ☐ Yes ☒ No

24. Conflict of Interest *(Conflict of interest refers to any situation in which financial, professional, or personal obligations may compromise or present the appearance of compromising an individual's professional judgment in designing, conducting, analyzing, or reporting research.)*

Does a conflict of interest exist with this study? ☒ No ☐ Yes, explain: _____

25. Project Enclosures (Check all appropriate boxes and include the items with the Proposal Form)

☒ Informed Consent Form(s)

☒ Child/Youth Assent Form

☐ Grant/Contract Application/Proposal

☒ Facility Authorization Letter

☐ Debriefing Script
☒ Research Instruments (Surveys, Questionnaires, etc.)
☐ Waiver of Documentation of Consent
☐ Recruitment Information (Ads, Web postings, letters, etc.)
☐ Other items: _____

26. Complete Description of the Study Procedures

This project is being conducted as part of the normal educational practices of the student dental doctor in their dental school curriculum. All fourth year student dental doctors will be rotating through this program. Subjects who volunteer to participate in this oral health screening will be asked to complete a demographic questionnaire (attachment 1) pertaining to their oral health status, if possible, and allow a third and/or fourth-year student dental doctor, supervised by a UNLV SDM licensed dental faculty member, to perform an oral health screening and an oral soft tissue assessment. If the subject is not able to complete the questionnaire by themselves, a site staff employee will interview the subject and complete the questionnaire for him/her. A verbal script is attached (attachment 8) explaining the screening to those subjects who are unable to read or comprehend the screening protocol. The oral health and soft tissue screening is not a full dental examination. Each tooth will not be completely evaluated and dental radiographs (X-rays) will not be taken. The oral health screening is not meant to take the place of a complete dental examination. These screenings will result in advising client of need for treatment. Subjects will be given a treatment urgency form (attachment 3) and a dentist referral list (attachment 10) to chose from for follow-up treatment. The Rawson-Neal Psychiatric Hospital and Desert Regional Center have agreed to participate in the screening program (attachments11A and 11B). Also, a screening site protocol has been written (attachment 12) explaining the the steps to be taken upon the screeners arrival at the screening facility.

27. Investigator/Faculty Advisor/Student/Fellow Assurance

A. Investigator's Assurance:
I certify that the information provided in this application is complete and accurate. As Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations designated by the IRB. I agree to comply with all UNLV policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

- Performing the project by qualified personnel according to the approved protocol.
- Not changing the approved protocol or consent form with out prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).
- Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.
- Promptly reporting adverse events to OPRS in writing according to IRB guidelines.
- Arranging for a co-investigator to assume direct responsibility, if the PI will be unavailable to direct this research personally, as when on sabbatical leave or vacation.

_____	_____	_____
Principal Investigator's Name	Principal Investigator's Signature	Date
_____	_____	_____
Co-Principal Investigator's Name	Co-Principal Investigator's Signature	Date

B. Faculty Advisor Assurance: (Faculty Advisor must sign below if this is a student initiated research project.)
By my signature as advisor on this research application, I certify that the student/fellow investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accordance with the approved protocol. In addition:

- I agree to act as the liaison between the IRB and the student/fellow investigator with all written and verbal communications.
- I agree to meet with the student/fellow investigator on a regular basis to monitor the progress of the study.
- I agree to be available and to personally supervise the student/fellow investigator in solving problems, as they arise.

- I assure that the student/fellow investigator will promptly report adverse events to OPRS according to IRB guidelines.
- I will arrange for an alternate faculty advisor to assume responsibility if I become unavailable, as when on sabbatical leave or vacation.

Faculty Advisor's Name	Faculty Advisor's Signature	Date

(The faculty advisor must be a member of UNLV faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.)

C. Student/Fellow Investigator Assurance: (if applicable)

By my signature as Student/Fellow Investigator on this research application, I certify that I am knowledgeable about the regulations and policies governing research with human subjects and agree to conduct this particular study in accordance with the approved protocol. In addition:

- I agree to meet with my faculty advisor on a regular basis to discuss the progress of the study.
- I agree to meet with my faculty advisor to solve protocol issues, as they arise.
- I will promptly report adverse events to OPRS and my faculty advisor according to IRB guidelines.

Student/Fellow Investigator Name	Student/Fellow Investigator Signature	Date

Packing List for Oral Health Screenings
2007 Mental Health & Developmental Disabilities

Location Shipped To: _Dr. McClain – UNLV SDM
Date Shipped: ___
Screening Date: September 2007

Item	Amount Sent
Gloves	
Masks	
Flashlight	
Mouth Mirrors	
Cotton Tipped Applicators	
Paper Towels	
Hand Sanitizer	
Antibacterial Wipes	
Trash Bags	
Toothbrushes	
Toothbrush Covers	
Biohazardous Waste Stickers	
2"x2" gauze	
Packing tape	
Denture Brushes	
Patient Bibs	
Patient Bib Clips	
Safety Glasses for Patients	
Mouth Props	

Mental Health & Developmental Disabilities			
Oral Health Screening Project			
DEN 7454 - CLASS 2008			
Please enter your glove size in the columns provided after your name.			
The Oral Health Program will be ordering non-latex gloves for this project and would like to get an idea of what sizes to order.			
Last Name	**First Name**	**Glove Size**	
		MEDIUM	
		SMALL	
		LARGE	
		MEDIUM	
		LARGE	
		LARGE	
		LARGE	
		MEDIUM	
		MEDIUM	
		LARGE	
		SMALL	
		MEDIUM	
		SMALL	
		SMALL	
		LARGE	
		EXTRA SMALL	
		MEDIUM	
		EXTRA LARGE	
		EXTRA SMALL	
		SMALL	
		SMALL	
		SMALL	
		SMALL	
		LARGE	
		EXTRA LARGE	
		SMALL	
		LARGE	
		SMALL	
		LARGE	
		MEDIUM	
		EXTRA SMALL	
		SMALL	

		LARGE	
		EXTRA SMALL	
		LARGE	
		LARGE	
		MEDIUM	
		LARGE	
		LARGE	
		MEDIUM	
		MEDIUM	
		MEDIUM	
		LARGE	
		SMALL	
		EXTRA LARGE	
		MEDIUM	
		MEDIUM	
		MEDIUM	
		MEDIUM	
		EXTRA LARGE	
		SMALL	
		SMALL	
		SMALL	
		EXTRA SMALL	
As of 8-21-07:	**Current Inventory:**	**Need to Order:**	
5 wear extra small	XS=0	XS = 2 boxes	
15 wear small	small=2 boxes=100 patients	small=4 boxes	
15 wear medium	med=17 boxes=850 patients	medium=1 box	
15 wear large	large=23 boxes=1,150 patients		
4 wear extra large	XL=5 boxes=250 patients		

Saturdays
9-22-07
9-29-07
10-06-07
10-13-07
10-20-07
11-03-07
11-17-07

Desert Regional Center - Oral Health Screening Schedule

Primary Nurse: _____ Phone Number: _____

Secondary Nurse: _____ Phone Number: _____

Portable Chair Number: _____ _____ (1 through 4)

Date: ___ _____

TIME	CLIENT	TIME	CLIENT
9:00 AM		**12:40 PM**	
9:20 AM		**1:00 PM**	
9:40 AM		**1:20 PM**	
10:00 AM		**1:40 PM**	
10:20 AM		**2:00 PM**	
10:40 AM		**2:20 PM**	
11:00 AM		**2:40 PM**	
LUNCH 11:30-12:30		**3:00 PM**	

Note to DRC Staff: Maximum of 60 patients can be scheduled on each Saturday, one for each of the 4 portable dental chairs

Screener: _____ Recorder: _____

EDUCATIONAL AFFILIATION AGREEMENT

AFFILIATION AGREEMENT

This Affiliation Agreement (the "Agreement") is made as of this 3rd day of September, 2007 by and between Rawson Neal Psychiatric Hospital ("Clinical Facility") and the Board of Regents of the Nevada System of Higher Education, acting on behalf of the University of Nevada, Las Vegas ("University").

WHEREAS, University desires to offer to its students in its Dental program clinical learning experience through the application of knowledge and skills in actual patient-centered clinical situations; and

WHEREAS, Clinical Facility has agreed to make its facility available to University for such purposes; and

WHEREAS, University and Clinical Facility desire to provide in writing a full statement of their respective rights, obligations, and duties in connection with their mutual agreement to cooperate to further the above-described purposes;

NOW, THEREFORE, in consideration of the mutual promises and undertakings contained herein, the parties agree as follows:

I. RESPONSIBILITIES OF UNIVERSITY

A. University shall be responsible for providing classroom theory and practical instruction to its students prior to the students beginning their clinical learning experience with Clinical Facility.

B. University shall be responsible for providing orientation of its students to the clinical experience at Clinical Facility.

C. University shall be responsible for planning and implementing the clinical learning experience to be gained by its students while at Clinical Facility's facility ("Program"). This Program shall be shared with Clinical Facility.

D. University shall be responsible for the preparation of student/patient assignments and rotation plans for each student and will coordinate such assignments and rotations with Clinical Facility.

E. University will make all reasonable efforts to ensure that its students and instructional personnel comply with all applicable rules, regulations, and professional ethics of Clinical Facility.

F. University will maintain oral and written communication with Clinical Facility regarding student performance and evaluation, absences and assignments of students, and other pertinent information.

G. University shall be responsible for evaluating its students' performance at Clinical Facility.

H. University shall retain the discretion of withdrawing any student whose work or conduct may have a detrimental effect on the Program or whose progress and achievement do not justify his or her continuance in the Program.

I. University shall be responsible for requiring each Program participant to sign a Statement of Responsibility in the form attached hereto as Exhibit A, and a Statement of Confidentiality in the form attached hereto as Exhibit B.

J. University will endeavor to advise Program participants to have appropriate medical insurance coverage that will adequately cover them for any injury or illness which may result from their participation in the Program.

II. RESPONSIBILITIES OF CLINICAL FACILITY

A. Clinical Facility shall accept the students assigned to the Program by University and cooperate in the orientation of all Program Participants at Clinical Facility.

B. Clinical Facility shall provide opportunities for Program participants to observe and assist in various patient care responsibilities. However, responsibility for the care of patient's remains at all times with Clinical Facility.

C. Upon the request of University, Clinical Facility shall assist University in evaluating the performance of each Program participant. Clinical Facility agrees, however, that University remains solely responsible for the evaluation and grading of Program participants.

D. Clinical Facility shall treat any evaluation of Program participant in confidence and will not release or disclose such information to third parties without the written consent of the student concerned or a court order. Clinical Facility shall inform University of all such requests or court order.

E. Clinical Facility shall designate a representative who will act as a liaison between University, Clinical Facility, and students.

F. Clinical Facility agrees that University student and faculty participants in the Program will not ride in any fixed or rotary-winged aircraft or ride or drive in any ambulance during the period of the participants' clinical education experience with Clinical Facility.

G. Clinical Facility will be responsible for arranging immediate emergency care for Program participants in the event of an accident or injury or illness, while Program participants are receiving clinical training at Clinical Facility's premises. Except for the negligent or intentional acts or omissions of Clinical Facility, its directors, officers, employees, or agents, Clinical Facility shall not be responsible for any costs involved in providing such emergency care, follow-up care, or hospitalization, nor shall University.

III. MUTUAL RESPONSIBILITIES

University and Clinical Facility shall cooperate to fulfill the following responsibilities:

A. University and Clinical Facility shall each inform student participants that their participation in the Program does not entitle them to future employment with Clinical Facility.

B. University and Clinical Facility shall each inform Program participants that they are not employees of Clinical Facility and as such are not eligible for wages, workers ' compensation, or other benefits otherwise available to Clinical Facility employees for any services provided in connection with this Program.

IV. HEALTH OF PARTICIPANTS

Program participants shall be responsible for arranging for their medical care and/or treatment, if necessary, including transportation, in case of illness or injury while participating in the Program with Clinical Facility. Except as provided for in Exhibit A attached hereto, Clinical Facility shall not be financially responsible or otherwise responsible for said medical examination, medical care and treatment, nor shall University.

V. WITHDRAWAL OF PROGRAM PARTICIPANTS

A. Clinical Facility may immediately remove from its premises any Program participant who poses an immediate threat or danger to Clinical Facility personnel or patients or to the quality of medical services or for unprofessional behavior.

B. Clinical Facility may request University to withdraw a Program participant from the Program when his or her clinical performance is unsatisfactory to Clinical Facility or his or her behavior, in Clinical Facility's discretion, is disruptive or detrimental to Clinical Facility and/or its patients. In such event, said Program participant's participation in the Program shall cease immediately. Clinical Facility acknowledges and understands, however, that only University can dismiss a Program participant from the Program.

EDUCATIONAL AFFILIATION AGREEMENT

VI. FEE SCHEDULE AGREEMENT

Unless provided for in this Agreement, neither Clinical Facility nor University shall charge the other for services provided pursuant to this Agreement.

VII. TERM AND TERMINATION

A. This Agreement is for a term of three (3) years.

B. Either party may terminate this Agreement without cause upon thirty (30) days written notice to the other party. Said termination will be effective at the completion of the semester in which the notice is given, thus allowing students to complete their clinical learning experience during the semester in which the termination notice is given.

VIII. INSURANCE AND INDEMNIFICATION

A. University will maintain medical malpractice insurance for Program participants in the minimum amount of One Million Dollars ($1,000,000) for each occurrence and Three Million Dollars ($3,000,000) aggregate. This minimum amount may represent coverage in any combination of primary and excess amounts, and University shall provide Clinical Facility with a certificate of insurance evidencing that this coverage has been obtained.

B. Clinical Facility will maintain medical malpractice insurance in the minimum amount of One Million Dollars ($1,000,000) for each occurrence and Three Million Dollars ($3,000,000) aggregate. This minimum amount may represent coverage in any combination of primary and excess amounts, and Clinical Facility shall provide University with a certificate of insurance evidencing that this coverage has been obtained.

C. To the extent limited in accordance with NRS 41.0305 to NRS 41.039, University hereby agrees to indemnify, defend, and hold harmless Clinical Facility, its directors, officers, employees and agents from and against any and all liability, losses, damages, judgments, claims, or causes of action and expenses connected therewith (including reasonable attorney's fees), arising or asserted to have arisen, directly or indirectly, by or as a result of the negligence or willful misconduct of University, its faculty, employees, or agents in the performance of University's responsibilities under this Agreement. In accordance with Chapter 41 of the Nevada Revised Statutes, University will assert the defense of sovereign immunity as appropriate in all cases, including malpractice and indemnity actions. Claims against University, its officers, employees, or agents are limited to $50,000 per person per cause of action.

Clinical Facility hereby agrees to indemnify, defend, and hold harmless University, its officers, employees and agents from and against any and all liability, losses, damages, judgments, claims and causes of action and expenses connected therewith (including reasonable attorney's fees), arising or asserted to have arisen, directly or indirectly, by or as a result of the negligence or willful misconduct of Clinical Facility, its directors, officers, employees or agents in the performance of Clinical Facility's responsibilities under this Agreement.

D. In the event that each of the parties is found to be at fault, then each shall bear its own costs and attorney's fees and its proportionate share of the judgment or settlement based on its percentage of fault.

E. Clinical Facility shall have in place workers' compensation insurance as required by Clinical Facility's state law.

Coverage shall be on an occurrence basis and shall be at least as broad as ISO 1996 form CG 00 01 and shall cover liability arising from premises, operations, independent contractors, completed operations, personal injury, products, and liability assumed under contract.

IX. NO DISCRIMINATION

EDUCATIONAL AFFILIATION AGREEMENT

Neither University nor Clinical Facility shall discriminate on the basis of race, national origin, religion, sex, sexual orientation, age, marital status, disability, or veteran status in either the selection of students for participation in the Program, or as to any aspect of the clinical training. With respect to disability, however, the disability must not be such as would, even with reasonable accommodation, prevent participants from performing the essential requirements of the clinical Program.

X. CONFIDENTIALITY

University agrees to keep strictly confidential and hold in trust all confidential information of Clinical Facility and/or its patients and not disclose or reveal any confidential information to any third party without the express prior written consent of Clinical Facility.

XI. ENTIRE AGREEMENT

This Agreement and its accompanying Exhibits contain the entire agreement and understanding of the parties with respect to the subject matter hereof and supersede all prior agreements, contracts, and understanding, oral or written, and all other communications between the parties relating to such subject matter.

The terms and conditions of this Agreement may be amended only by written instrument executed by both parties. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

XII. SEVERABILITY

If any provision of this Agreement is held to be invalid, illegal or unenforceable for any reason, the validity, legality and enforceability of the remaining provisions contained in this Agreement shall not in any way be affected or impaired thereby.

XIII. NO WAIVER

Any failure of a party to enforce that party's right under any provision of this Agreement shall not be construed or act as a waiver of said party's subsequent right to enforce any of the provisions contained herein.

XIV. CAPTIONS

The captions contained herein are for reference purposes only and shall not affect the meaning or interpretation of provisions of this Agreement.

XV. BINDING EFFECT AND ASSIGNMENT

This Agreement, along with its benefits and obligations, shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, successors, and assigns. No portion of this Agreement may be assigned, in whole or in part, by any party hereto without the prior written consent of the other party.

XVI. GOVERNING LAW

This Agreement shall be governed by, and enforced in accordance with, the laws of the State of Nevada, and the venue for any action relating to this Agreement shall be in the Eighth Judicial District Court, Clark County, State of Nevada.

XVII. NOTICES

Any notice required or permitted by this Agreement shall be in writing and shall be deemed given at the time it is deposited in the United States Mail, postage prepaid, certified or registered mail, return receipt requested, addressed to the party to whom it is to be given as follows:

EDUCATIONAL AFFILIATION AGREEMENT

CLINICAL FACILITY	**RAWSON NEAL PSYCHIATRIC HOSPITAL**
FACILITY	**UNLV SCHOOLOF DENTAL MEDICINE**
SIGNATURE AUTHORITY	Mildred Arroyo McClain, PhD
SIGNATURE AUTHORITY TITLE	Assistant Professor and Community Outreach Coordinator
FACILITY NAME	University of Nevada, Las Vegas
FACILITY ADDRESS	1001 Shadow lane, MS 7410
FACILITY CITY STATE & ZIP	Las Vegas NV 89106-4124

IN WITNESS HEREOF, the parties hereto have executed this Agreement the day and year first above written.

FACILITY

_____
SIGNATURE AUTHORITY
SIGNATURE AUTHORITY TITLE

_____
Date

UNLV SCHOOLOF DENTAL MEDICINE

Recommended by:

_____
Mildred Arroyo McClain, PhD
Assistant Professor and Community Outreach Coordinator

_____
Date

Approved by:

_____
Dr. Michael Bowers
Senior Vice Provost for Academic Affairs
University of Nevada, Las Vegas
Agent of University and
Nevada System of Higher Education
On behalf of the University of Nevada, Las Vegas

_____
Date

EXHIBIT A

STUDENT STATEMENT OF RESPONSIBILITY

For and in consideration of the benefit provided me in the form of clinical learning experience (Program) with Rawson Neal Psychiatric Hospital ("Clinical Facility"), under the Affiliation Agreement "University") and Clinical Facility, I,_____, a dental student at the University of Nevada, Las Vegas ("UNLV") School of Dental Medicine, on my own behalf and on behalf of my heirs, assigns and personal representative (if deceased), do hereby covenant and agree to assume all risks and be solely responsible for any injury or loss (including death) sustained by me while participating in the Program operated by University at Clinical Facility, unless such injury or loss (including death) arises solely out of the negligence or willful misconduct of Clinical Facility or University or their respective directors, officers, employees, or agents .

I will abide by Clinical Facility's Code of Conduct and all of Clinical Facility's policies, procedures, rules and regulations throughout the clinical learning experience with Clinical Facility. I will notify both UNLV and designated Clinical Facility representative (liaison) if, for any reason, I am unable to report to Clinical Facility for a scheduled clinical rotation or to participate in the Program.

I agree that I am solely responsible for my maintenance, support and living expenses and transportation to and from Clinical Facility premises throughout the period of my clinical learning experience with Clinical Facility.

I hereby acknowledge and agree that the State of Nevada, including its Board of Regents of the Nevada System of Higher Education, UNLV, Clinical Facility, and their respective directors, officers, employees and agents (in their individual and official capacities) will not defend, indemnify or otherwise compensate and/or reimburse me for any acts or omissions committed by me which are found to be outside the scope of the clinical learning experience with Clinical Facility.

I understand and agree that my status with Clinical Facility throughout the period of my clinical learning experience with Clinical Facility is that of a Nursing student receiving clinical education. For this reason, I can have no expectation of receiving compensation from, or future employment with, either Clinical Facility or University.

I hereby acknowledge and agree that I have been offered the opportunity (if desired) to consult with my own attorney concerning the contents of this Student Statement of Responsibility before signing it.

I warrant that I am at least 18 years of age; that I have read and understand the contents of this document; and that I sign it freely and without reliance upon any representations or promises by the State of Nevada, including its Board of Regents of the Nevada System of Higher Education, UNLV, Clinical Facility or their respective directors, officers, employees or agents.

Dated this_____ day of_____, 200_.

_____

Signature of Program Participant

EXHIBIT B

STUDENT CONFIDENTIALITY STATEMENT

I, _____, a Dental student at the University of Nevada, Las Vegas ("UNLV") School of Dental Medicine, in consideration of the clinical learning experience with Rawson Neal Psychiatric Hospital ("Clinical Facility") being made available to me under the Affiliation Agreement between the Board of Regents of the Nevada System of Higher Education, on behalf of the University of Nevada, Las Vegas and Clinical Facility, to which this Student Confidentiality Statement is being attached as an Exhibit, hereby recognize that, while with Clinical Facility, medical records, patient care information, personnel information, reports to regulatory agencies, conversations between or among any healthcare professionals are considered privileged and should be treated with utmost confidentiality.

I agree, under penalty of law, not to disclose to any person or persons, except authorized clinical staff and associated personnel of Clinical Facility, the above-listed information and further agree not to reveal to any third party any confidential information of Clinical Facility, except as required by law or as authorized by Clinical Facility.

I hereby acknowledge and agree that I have been offered the opportunity (if desired) to consult with my own attorney concerning the contents of this Student Confidentiality Statement before signing it.

I warrant that I am at least 18 years of age; that I have read and understand my obligations under this Student Confidentiality Statement; and that I sign it freely and without reliance upon any representations or promises by the State of Nevada, including its Board of Regents of the Nevada System of Higher Education, UNLV, Clinical Facility or their respective directors, officers, employees or agents.

Dated this _____ day of _____, 200_.

_____

Signature of Program Participant

The Agreement

HIPAA Requirements

To the extent applicable, Clinical Facility agrees to comply with the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. Section 1320d ("HIPAA") and any current and future regulations promulgated thereunder, including, without limitation, the federal privacy regulations contained in 45 C.F.R. Parts 160 and 164 (the "Federal Privacy Regulations"), the federal security standards contained in 45 C.F.R. Part 142 (the "Federal Security Regulations"), and the federal standards for electronic transactions contained in 45 C.F.R. Parts 160 and 162, all collectively referred to herein as "HIPAA Requirements." Clinical Facility agrees not to use or further disclose any Protected Health Information (as defined in 45 C.F.R. Section 164.501) or individually Identifiable Health Information (as defined in 42 U.S.C. Section 1320d), other than as permitted by HIPAA Requirements and the terms of this Agreement.

Clinical Facility will make its internal practices, books, and records relating to the use and disclosure of Protected Health Information available to the Secretary of Health and Human Resources to the extent required for determining compliance with the Federal Privacy Regulations.

COMPANY NAME Rawson Neal Psychiatric Hospital

SIGNATURE _____

TITLE _____

SOUTHERN NEVADA ADULT MENTAL HEALTH SYSTEM

RAWSON-NEAL PSYCHIATRIC HOSPITAL
Las Vegas, Nevada

INFORMED CONSENT AND COMPETENCY ASSESSMENT FORM

Patient Name_____

Unit _____ Date of Assessment: _____

1. **Does the patient know and understand the nature and purpose of the dental screening procedure? _____yes _____no**
2. **Does the patient know the risks and benefits of undergoing a dental screening? _____yes _____no**
3. **Does the patient know that participation in the dental screening is voluntary? _____yes _____no**
4. **Does the patient know that he can withdraw form the dental screening at anytime if he/she desires to do so? _____yes _____no**

_____ _____M.D.
Staff Psychiatrist/ Printed Name Signature

Biomedical IRB – Full Board Review
Revisions Request

DATE: July 30, 2007

TO: **Dr. Mildred McClain,** School of Dental Medicine

FROM: Office for the Protection of Research Subjects

RE: Notice of IRB Action
Protocol Title: **Governor's Commission Oral Health Screening on Special Needs Population**
OPRS# 0706-2399

This memorandum is notification that the project referenced above has been reviewed by the UNLV Biomedical Institutional Review Board (IRB) as indicated in regulatory statutes 45 CFR 46.

Thank you for submitting a Protocol Package describing your research. After reviewing the Protocol Package and discussing your planned research activities, the IRB has determined that your work can be reviewed through an Exempt Research category only if separate descriptions of the educational and research components are provided.

The present protocol form describes the educational and research components as one program. However, based upon our phone conversation, it seems that the educational component will occur regardless of a research question being asked. Instead of describing both components concurrently, please describe the educational program that would exist regardless of a research question being asked and what activities are only being done because a research question is being asked. This approach will also mean that the consent form will need to be revised to inform potential subjects about what activities are related to the research study (vs. the dental screening program). In order to assist this revision, completion of the Exempt Research Form may be better suited to describe the activities being conducted rather than changing the current protocol proposal form. You may find the Exempt Research Form on the OPRS website at: http://research.unlv.edu/OPRS/forms/ExemptResearchForm.doc.

If you have questions or require any assistance, please contact the Office for the Protection of Research Subjects at OPRSHumanSubjects@unlv.edu or call 895-2794.

UNLV
CELEBRATING FIFTY YEARS
Office for the Protection of Research Subjects

IRB Received Date Stamp—Office Use Only	IRB Protocol Number—Office Use Only

Exempt Research Application Form

Applicable Policy – 45 CFR 46.101 (b)

Evidence of CITI certification (www.citiprogram.org) must be submitted with this application form.

Instructions:

1. Complete this application if you believe your study qualifies as exempt research based on the categories below. The UNLV IRB will make the final determination for approval of exempt research projects. The exemption approval must be granted in writing by the UNLV IRB before research can begin on the project.
2. Exempt research must adhere to the same ethical principles governing all research.
3. Exempt applications must include copies of informed consent/assent, questionnaires/surveys, advertisements, etc.
4. If the IRB determines the research to be non-exempt the project must be resubmitted with the completed Research Protocol Proposal Form to again proceed through the IRB review process.

1. Submittal Date: 8/22/2007

2. Duration of Study

Anticipated Start Date: 9/22/2007
Anticipated Termination Date: 9/22/2008

3. Research Protocol Title

Governor's Commission Oral Health Screening on Special Needs Population

4. Investigator(s) Contact Information

(One person must be designated as the PI. The PI must be a UNLV faculty or professional staff member in all cases involving studies carried out by students or fellows.)

A. Principal Investigator (*Name and Credentials*): Mildred Arroyo McClain, PhD

☒ Faculty ☐ Faculty Advisor ☐ Professional Staff

School/College/Center: School of Dental Medicine
Department: Professioanl Studies Mail Stop: 7410
Mailing Address: 1001 Shadow Lane
Phone Number: (702) 774-2642 Fax Number: (702) 774-2721
E-Mail Address: millie.mcclain@unlv.edu

B. Student/Fellow Investigator (*Name and Credentials*): _____

☐ Undergraduate ☐ Masters ☐ Doctoral ☐ Fellow

School/College/Center: _____
Department: _____ Mail Stop: _____
Mailing Address: _____
Phone Number: _____ Fax Number: _____
E-Mail Address: _____

NOTE: All student/fellow initiated research must be submitted as an independent project with the Faculty Advisor listed

as the Principal Investigator. The Faculty Advisor must sign the Faculty Advisor Assurance statement in Section 5B. The Student/Fellow Investigator must sign the Student/Fellow Investigator Assurance statement in Section 5C.

C. PLEASE COMPLETE ONLY IF APPLICABLE

Co-Principal Investigator *(Name and Credentials):* R. Michael Sanders, DMD, EdM

☒ Faculty ☐ Professional Staff

School/College/Center: School of Dental Medicine

Department: Clinical Sciences Mail Stop: 7410

Mailing Address: 1001 Shadow Lane

Phone Number: (702) 774-2660 Fax Number: (702) 774-2721

E-Mail Address: michael.sanders@unlv.edu

5. Project Details

A. Describe the purpose of the project and how you will conduct it. This project has an educational and a reseach component. As part of the student dental education component, the study population will be given a free oral health and soft tissue screening. At the conclusion of this study, the student dental doctor will be able to: 1) discuss the etiology and prevalence of common disabling conditions; 2) describe barriers to dental care for disabled and other special needs individuals; 3) describe the psychological and social factors which impact disabled and other special needs individuals' ability to seek and accept dental care; 4) describe significant systemic and oral conditions which should be considered in planning dental care to disabled and other special needs individuals; and 5) describe significant treatment planning considerations and operational procedural modifications in providing dental care for individuals with special needs. As part of the research component, findings will be reported to the Governor's Commission on Mental Health and Developmental Services so the results may be compared to the access to oral health care goals addressed in Healthy People 2010 objectives for he Nation. Participants or their legally authorized representative will be asked to complete a demographic questionnaire (Attachment 1) pertaining to their oral health, and allow a fourth-year student dental doctor, supervised by a UNLV School of Dental Medicine licensed faculty dentist, to perform the free oral health screening. If the subject is not able to complete the questionnaire by themselves, a site staff employee will interview the subject and complete the questionnaire for him/her. A verbal script is attached (Attachment 2) explaining the screening to those subjects who are unable to read or comprehend the screening protocol. The oral health and soft tissue screening is NOT a full dental examination. Each tooth will not be completely evaluated and dental radiographs (X-rays) will not be taken. Screening indices on the free oral health screening form (attachment 3) will be recorded for analysis of caries indices and access to care. These screenings will result in advising client of need for treatment urgency. Subjects will be given a treatment urgency form (attachment 4) and a dentist referral list (attachment 5) to chose from for follow-up treatment. The oral health screenings will be conducted at the Desert Regional Center (DRC) and Rawson Neal Psychiatric Hospital (RNPH) facilities using portable dental equipment, mouth mirrors, mouth props (attachment 6), tongue depressors, and gauze, Prior to the oral health screening, there will be an in-service for facility site staff explaining the research subjects rights (attachment 7) and the oral health screening. This in-service will be conducted by the co-principle investigator, R. Michael Sanders, DMD, EdM. Only those subjects from the DRC and RNPH that have returned a signed consent form(s) will be allowed to participate in the free oral health and soft tissue screening (Attachment 8, Informed Consent will be used for adult subjects 18 years of age and older; Attachment 9, Youth Assent/Agreement will be used for subjects 12 to 17 years old; Attachment 10, Parental Permisison, will be used for all subjects under 18 yers of age). There will be a verbal script (Attachment 2) for those subjects under age 12 and for subjects with comprehension incapabilities. Informed consent will be explained to subjects, parents and/or their legally authorized representative by the site staff at each facility since subjects are residents of the facilities. The site staff person who explains the screening and consent process will also initial and

date the consent form(s) acknowledging that they have explained the consent form and the oral health and soft tissue screening examination to the client (Attachments 8, 9, 10). A screening site protocol has been written (Attachment 11) for the student dental doctors explaining the the steps to be taken upon their arrival at the screening facility.

B. Describe study population/specimens/data to be studied. The research findings will address if the special needs population have a higher incidence of caries experience and more difficulty with access to care issues than the general population. Approximately 900 special needs subjects from DRC and appoximately 50 subjects from RNPH will have free oral health and soft tissue screenings. This project is being conducted as part of the normal educational practices of the student dental doctor in their dental school curriculum. All fourth year student dental doctors will be rotating through this program. The RNPH and DRC have agreed to participate in the screening and research program (Attachments12A Facility Authorization DRC and 12B Facility Authorization RNPH). Data collected will include information on oral hygiene, areas of discomfort in the mouth, removable prosthetics, caries experience, untreated caries, missing teeth, inflamation, calculus, suspicious soft tissue lesions, treatment urgency, and cooperation of patient.

C. Describe how the data will be protected. All information gathered in this screening will be numerically coded and kept completely confidential. All consented subjects will be assigned a random coded identifier by the Nevada State Health Division Oral Health Program statistician (Jim Jordan). This number will be used to document all data for reporting to the Governor's Commission on Mental Health and Developmental Services and application for oral health disparities grants. No reference will be made in written or oral materials produced by the study that could link the subject to this screening. All records will be stored in a locked cabinet in Building B, room 243, at the UNLV SDM for 3 years post completion of the screening after which Dr. McClain will monitor shredding of all information. No one other than the Nevada State Health Division Oral Health Bio-statistician (Jim Jordan) and the UNLV SDM Professional Studies Bio-statisitician (Dr. Marcia Ditmyer) will be allowed access to the data.

6. Exempt Research Category (Check the applicable category)**:**

☒	1)	Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
☐	2)	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
☐	3)	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
☐	4)	Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
☐	5)	Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
☐	6)	Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Investigator/Faculty Advisor/Student/Fellow Assurance

A. Investigator's Assurance:
I certify that the information provided in this application is complete and accurate. As Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations designated by the IRB. I agree to comply with all UNLV policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

- Performing the project by qualified personnel according to the approved protocol.
- Not changing the approved protocol or consent form with out prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).
- Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.
- Promptly reporting adverse events to OPRS in writing according to IRB guidelines.
- Arranging for a co-investigator to assume direct responsibility, if the PI will be unavailable to direct this research personally, as when on sabbatical leave or vacation.

Principal Investigator's Name	Principal Investigator's Signature	Date
Co-Principal Investigator's Name	Co-Principal Investigator's Signature	Date

B. Faculty Advisor Assurance: (Faculty Advisor must sign below if this is a student initiated research project.)
By my signature as advisor on this research application, I certify that the student/fellow investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accordance with the approved protocol. In addition:

- I agree to act as the liaison between the IRB and the student/fellow investigator with all written and verbal communications.
- I agree to meet with the student/fellow investigator on a regular basis to monitor the progress of the study.
- I agree to be available and to personally supervise the student/fellow investigator in solving problems, as they arise.
- I assure that the student/fellow investigator will promptly report adverse events to OPRS according to IRB guidelines.
- I will arrange for an alternate faculty advisor to assume responsibility if I become unavailable, as when on sabbatical leave or vacation.

Faculty Advisor's Name	Faculty Advisor's Signature	Date

(The faculty advisor must be a member of UNLV faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.)

C. Student/Fellow Investigator Assurance: (if applicable)
By my signature as Student/Fellow Investigator on this research application, I certify that I am knowledgeable about the regulations and policies governing research with human subjects and agree to conduct this particular study in accordance with the approved protocol. In addition:

- I agree to meet with my faculty advisor on a regular basis to discuss the progress of the study.
- I agree to meet with my faculty advisor to solve protocol issues, as they arise.
- I will promptly report adverse events to OPRS and my faculty advisor according to IRB guidelines.

Student/Fellow Investigator Name	Student/Fellow Investigator Signature	Date

Demographic Form

Study ID: _____ LocID: _____

Date of Birth

_____/____/_____ **(mm/dd/year)**

Gender

- ❑ Male
- ❑ Female

Race / Ethnicity (check all that apply)

- ❑ White
- ❑ Black/African American
- ❑ Asian
- ❑ Hispanic
- ❑ Native Hawaiian/Pacific Islander
- ❑ American Indian/Alaska Native

Education

- ❑ Less than High School
- ❑ High School graduate or G.E.D.
- ❑ Some Post High School
- ❑ College graduate

Smoking History

- ❑ Never smoked
- ❑ Quit smoking
- ❑ Currently smoke

1. About how long has it been since you last visited a dentist or a dental clinic? **(Please check only one)**

- ❑ Within the last 12 months
- ❑ More than 1 year ago, but not more than 3 years ago
- ❑ More than 3 years ago
- ❑ Never has been to the dentist

2. What was the main reason for your last visit? **(Please check only one)**

- ❑ Went in on own for check-up, examination or cleaning
- ❑ Was called in by the dentist for check-up, examination or cleaning
- ❑ Something was wrong, bothering or hurting
- ❑ Went for treatment of a condition that dentist discovered at earlier check-up or examination
- ❑ Other
- ❑ Never has been to the dentist

3. Do you have any kind of insurance that pays for some or all of your MEDICAL OR SURGICAL CARE? Include health insurance obtained through employment or purchased directly, as well as government programs like Medicaid.

- ❑ Yes
- ❑ No

4. Do you have any kind of insurance that pays for some or all of your DENTAL CARE? Include health insurance obtained through employment or purchased directly, as well as government programs like Medicaid.

- ❑ Yes
- ❑ No

5. During the past 12 months, was there a time when you needed dental care but could not get it at that time?

- ❑ Yes (Please go to Question 6)
- ❑ No (You are done with the questionnaire)

6. The last time you could not get the dental care you needed, what was the main reason you couldn't get care? **(Check all that apply)**

- ❑ Could not afford it
- ❑ No insurance
- ❑ Dentist did not accept Medicaid/insurance
- ❑ Speak a different language
- ❑ No way to get there
- ❑ Didn't know where to go
- ❑ No dentist available
- ❑ Not a serious enough problem

- ❑ Wait is too long in clinic/office
- ❑ Health of another family member
- ❑ Difficulty in getting appointment
- ❑ Dentist hours are not convenient
- ❑ Don't like/believe in dentists
- ❑ Other reason

7. List all of the client's current medications:

_____ _____

_____ _____

_____ _____

8. List the client's International Diagnostic codes:

_____ _____

_____ _____

_____ _____

Oral Health Screening Form

Date _____ Screener ID _____ Supervisor ID _____

Recorder ID _____

1 How often do you clean your mouth?
- o Once or more a day
- o 2 to 6 times a week
- o Once a week
- o Less than once a week
- o Not sure

2 Pain inside mouth?
- o Yes o No
  - o Teeth
  - o Other

3 May I look at your teeth today?
- o Yes
- o Client refused (go to # 11)

4 Edentulous?
- o Yes (go to # 10)
  - o Dentures
  - o No dentures
- o No (answer all questions)

5 Caries experience?
- o Yes o No

6 Untreated decay?
- o Yes o No

7 Missing teeth?
- o Yes o No

8 Inflammation?
- o Yes o No
  - o Mild
  - o Moderate
  - o Severe

9 Calculus Present?
- o Yes o No

10 Suspicious soft tissue lesions?
- o Yes o No

11 Treatment urgency
- o No obvious problem/Needs routine preventative care
- o Needs restorative care
- o Urgent care
  - o Pain
  - o Swelling
  - o Suspicious lesion
- o Unknown - client refused to participate

12 How difficult was it to screen the client?
- o Not difficult at all
- o Mildly difficult
- o Moderately difficult
- o Very difficult

Verbal Instruction/Permission Script
(Child or reading challenged adult)

Hello. My name is _____. I will be looking in your mouth today to see if your teeth have any cavities. I will be using a small mirror that goes in your mouth to look your teeth. You will lie back in the chair and put on these colored glasses. (Show the patient the glasses.) I will turn on a light to help me look in your mouth. It will not hurt and will only take a few minutes. All you have to do is hold your mouth open. If you have a problem holding your mouth open while I look in it, I can put this (Show the patient the mouth prop.) between your teeth to help you. It doesn't hurt and may make it easier for you to do this. (Give them the name of your partner) _____ is here to help us. He/she will be asking some things that I will answer. These are things I need to know about your mouth and teeth. I will also put my fingers in your mouth to feel the inside of your cheeks. This will not hurt. I will ask you to stick your tongue out so that I can look at it. When you stick your tongue out I will put some gauze on your tongue. (Show the patient the gauze.) I will hold your tongue so that I can look at it. This may feel funny, but it will not hurt. Please tell me if you do not like what I am doing and I will stop. Thank you for helping me. You are a very good helper.

Treatment Urgency:

- No Obvious Problem/Needs Routine Preventive Care
- Needs Restorative (Treatment) Care
- Urgent Care (Pain or Swelling Present)
- Suspicious soft tissue area

Urgencia del Tratamiento

- No hay problemas obvios; requiere examen rutinario
- Requiere restauraciones (tratamiento) dentales
- Requiere cuidado inmediato (se presenta con hinchazón o dolor)
- Area suave sospechosa de tejido

Dental Referral List

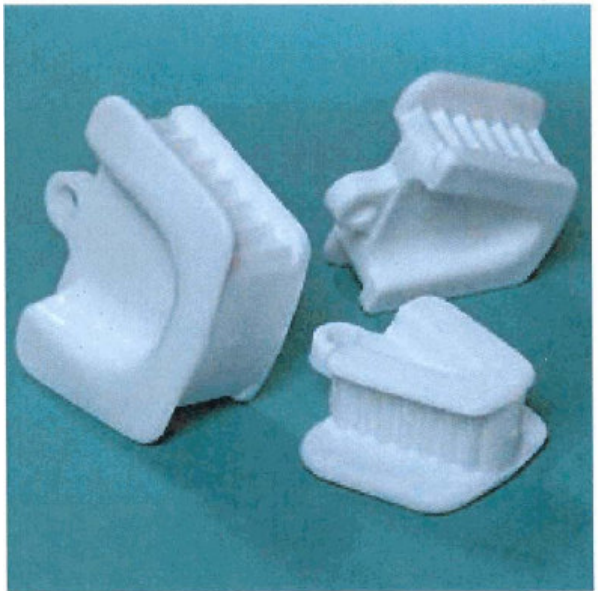
Patricia Craddock, DDS
820 South 7th Street, Suite A
Las Vegas, NV 89101
(702) 678-1835

UNLV School of Dental Medicine
1700 W. Charleston Ave., Building A
Las Vegas, NV 89106
(702) 774-2400

University Medical Hospital
Emergency Room
1800 W. Charleston Blvd.
Las Vegas, NV 89102
(702) 383-2000

You may also contact your family dentist for follow-up treatment

Attachment 6 – Mouth Prop



EXTND Mouth Props

Full featured, single-use props

EXTND™ Disposable Mouth Props save sterilization time and expense. Non-distortable white plastic construction with traditional ridged bite channels and safety line eyelets. Molded in single-use white plastic. 48 props per package in sizes S, M, L.

UNLV
UNIVERSITY OF NEVADA LAS VEGAS

Department of Professional Studies
School of Dental Medicine

TITLE OF STUDY: Governor's Commission Oral Health Screening on Special Needs Population

INVESTIGATOR(S): Mildred A. McClain, PhD and R. Michael Sanders, DMD, EdM

CONTACT PHONE NUMBER: (702) 774-2642

Study ID:_____ Loc. ID:_____

Informed Consent

Purpose of the Study
You are invited to participate in a free oral health screening and research study. The purpose of this screening is to evaluate the oral health of the mentally disabled and special needs population.

Participants
You are being asked to participate in the oral health screening based upon a request by the Governor's Commission on Mental Health and Developmental Services for more information on the oral health of the mentally disabled and special needs population. You can also agree to allow the information collected during the screening for a research study.

Procedures
If you volunteer to participate in this oral health screening, you will be asked to complete: (1) a questionnaire pertaining to your oral health, and (2) allow a fourth-year student dental doctor, supervised by a UNLV School of Dental Medicine faculty member, to perform an oral health screening. This is **NOT** a full dental examination. Each tooth will not be completely evaluated and dental radiographs (X-rays) will not be taken. The oral health screening is not meant to take the place of a complete dental examination. It is your responsibility to pursue routine dental care on a regular basis. You can still participate in the oral health screening, even if you do not allow your screening information to be used for research.

Benefits of Participation
There *may or may not* be direct benefits to you as a participant in this screening. However, oral health screening will identify possible caries which will result in advising clients of need for treatment. Additionally we hope to learn the oral health status of the mentally disabled and special needs population. These findings will be reported to the Governor's Commission on Mental Health and Developmental Services so they may look at access to oral health care goals addressed in Healthy People 2010 objectives for he Nation.

Risks of Participation
This oral health screening includes only minimal risks in that you may become uncomfortable with answering questions or having someone complete an oral health screening.

Cost /Compensation
There *will not* be financial cost to you to participate in this screening. The screening will take about 15 to 20 *minutes* of your time. You *will not* be compensated for your time. *The University of Nevada, Las Vegas may not provide compensation or free medical care for an unanticipated injury sustained as a result of participating in this screening.*

Contact Information
If you have any questions or concerns about the screening, you may contact Mildred A. McClain, PhD, at **702-774-2642.** For questions regarding the rights of screening participants, any complaints or comments regarding the manner in which the screening is being conducted you may contact **the UNLV Office for the Protection of Research Subjects at 702-895-2794.**

Voluntary Participation
Your participation in this screening is voluntary. You may refuse to participate in this screening. You are encouraged to ask questions about this screening at the beginning or any time during the screening. You can also choose to not allow data collected during the screening for the research portion of this project.

Confidentiality
All information gathered in this screening will be numerically coded and kept completely confidential. No reference will be made in written or oral materials that could link you/the client to this screening. All records will be stored in a locked facility at UNLV SODM for 3 years after completion of the screening after which Dr. McClain will monitor shredding of all information.

Participant Consent
By signing this form the client or legally authorized representative agrees to allow the client to participate in an oral health screening provided by a third and/or fourth-year UNLV SODM student dental doctor, under the supervision of a faculty licensed dentist. All screening information will be kept confidential.

___I only want to participate in the screening
___I allow my screening information to be used for research data

_____ _____
Print Name of Client Signature of Client

_____ _____
Print Name of Legally Authorized Representative (LAR) (if applicable) LAR Signature (if applicable)

Date: ___/____/_____
mm dd yyyy

I acknowledge that I have explained the oral health screening examination to the client and that the client understands what the procedure entails.

Initials: _____ Date: ___/____/__

Participant Note: Please do not sign this document if the Approval Stamp is missing or is expired.

University of Nevada Las Vegas
School of Dental Medicine
Department of Professional Studies
YOUTH ASSENT/AGREEMENT FORM

General Information:
Hello my name is Dr. Mildred Arroyo McClain. I am an Assistant Professor in the UNLV School of Dental Medicine, Department of Professional Studies. I am the researcher on this project. I am inviting you to have a free screening of your mouth for an education and research study. This is a voluntary screening and you have the right to not do it if you do not want to. Also, some of the questions may be ones you do not want to answer and you are not required to answer those questions if you do not want to.

Procedure:
If you agree to volunteer to have your mouth looked at, you will be asked to answer some questions about your mouth and going to the dentist. A dental student doctor will look in your mouth to see if you have any cavities or have ever had any cavities. The dental student doctor will ask you to stick out your tongue so that it can be checked, and feel the inside of your mouth and lips to see if there is anything that should not be there.

Benefits of Participation:
You can still have your mouth looked at even if you do not want to have what they find used for the study. By letting the dental student doctor look at your teeth, mouth, tongue and lips you will help us to know more about the mouths of people your age. If any cavities are found or if something does not look the way it should, you will be told.

Risks of Participation in:
There is no real risk in your having your mouth looked at. You may not want to answer some of the questions asked. You may choose not to answer any question that you do not want to answer.

Contact Information:
If you have any questions about the screening or if you have any negative or bad effects as a result of the screening, you may contact me at (702) 774-2642. For questions regarding the rights of research subjects, you may contact **the UNLV Office for the Protection of Research Subjects at (702) 895-2794.**

Voluntary Participation:
Your participation in this screening is voluntary. You may choose not to have your mouth looked at. You may also change your mind about the screening at any time and that will be okay. You may ask questions about this screening at the beginning or any time during the screening.

Confidentiality:
The screening will be done by University researchers and dental student doctors. All information gathered in this study will be kept completely confidential. No reference will be made in writing or in words that could link you to this screening. You will not be known in any way on the questionnaire and your responses will be secret. All information will be stored in a locked facility at UNLV School of Dental Medicine for at least 3 years after the screening is done. After 3 years, all information will be destroyed.

Please sign and return this consent form to the person who gave it to you.

___I only want to participate in the free screening
___I allow my screening information to be used for research study

_____ _____/____/_
Youth's Name (Please Print) Signature of Youth Date

I acknowledge that I have explained the oral health screening examination to the client and that the client understands what the procedure entails.

Initials: _____ Date: ___/____/_

UNLV
UNIVERSITY OF NEVADA LAS VEGAS

Department of Professional Studies

School of Dental Medicine

TITLE OF STUDY: Governor's Commission Oral Health Screening on Special Needs Population

INVESTIGATOR(S): Mildred A. McClain, PhD and R. Michael Sanders, DMD, EdM

CONTACT PHONE NUMBER: (702) 774-2642

Study ID:_____ Loc. ID:_____

Parent Permission

Purpose of the Study

Your child is invited to participate in a free oral health screening and research study. The purpose of this screening is to evaluate the oral health of the mentally disabled and special needs population.

Participants

You child is being asked to participate in the free oral health screening based upon a request by the Governor's Commission on Mental Health and Developmental Services for more information on the oral health of the mentally disabled and special needs population.

Procedures

If you allow your child to participate in this free oral health screening, you will be asked to complete: (1) a questionnaire pertaining to your child's oral health, and (2) allow a third and/or fourth-year student dental doctor, supervised by a UNLV School of Dental Medicine faculty member, to perform an oral health screening. This is **NOT** a full dental examination. Each tooth will not be completely evaluated and dental radiographs (X-rays) will not be taken. The oral health screening is not meant to take the place of a complete dental examination. It is your responsibility to assist your child to pursue routine dental care on a regular basis. Your child can still participate in the free oral health screening, even if you do not allow his/her information to be used for research.

Benefits of Participation

There *may or may not* be direct benefits to your child as a participant in this screening. However, oral health screening will identify possible caries which will result in advising clients of need for treatment. Additionally we hope to learn the oral health status of the mentally disabled and special needs population. These findings will be reported to the Governor's Commission on Mental Health and Developmental Services so they may look at access to oral health care goals addressed in Healthy People 2010 objectives for he Nation.

Risks of Participation

This oral health screening includes only minimal risks in that your child may become uncomfortable with answering questions or having someone complete an oral health screening.

Cost /Compensation

There *will not* be financial cost to you or your child to participate in this screening. The screening will take about 15 to 20 *minutes* of your child's time. You or your child *will not* be compensated for your time. *The University of Nevada, Las Vegas may not provide compensation or free medical care for an unanticipated injury sustained as a result of participating in this screening.*

UNLV
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Contact Information
If you have any questions or concerns about the screening, you may contact Mildred A. McClain, PhD, at **702-774-2642.** For questions regarding the rights of screening participants, any complaints or comments regarding the manner in which the screening is being conducted you may contact **the UNLV Office for the Protection of Research Subjects at 702-895-2794.**

Voluntary Participation
Your child's participation in this screening is voluntary. Your child may refuse to participate in this screening. You and your child are encouraged to ask questions about this screening at the beginning or any time during the screening.

Confidentiality
All information gathered in this screening will be numerically coded and kept completely confidential. No reference will be made in written or oral materials that could link you or your child to this screening. All records will be stored in a locked facility at UNLV SODM for 3 years after completion of the screening after which Dr. McClain will monitor shredding of all information.

Participant Consent
By signing this form you agree to allow your child to participate in an oral health screening provided by a third and/or fourth-year UNLV SODM student dental doctor, under the supervision of a faculty licensed dentist. All screening information will be kept confidential.

___I only allow my child to participate in the screening
___I allow my child's screening information to be used for research data

_____
Print Name of Child

_____ _____
Print Name of Parent Signature of Parent

_____ _____
Print Name of Legally Authorized Representative (LAR) (if applicable) LAR Signature (if applicable)

Date: ___/____/_____
mm dd yyyy

I acknowledge that I have explained the oral health screening examination to the client and that the client understands what the procedure entails.

Initials: _____ Date: ___/____/__

Participant Note: Please do not sign this document if the Approval Stamp is missing or is expired.

SCREENING SITE PROTOCOL

In order to make the oral health screening process as stress free as possible, the following is a list of the steps to be taken upon your arrival at the screening facility.

1. Arrive at the facility 30 minutes prior to the beginning of your screenings in order to get the screening area set up.

2. Upon arrival, go to the facility office and ask for the contact person. (Due to security you should not attempt to go directly to the screening area without checking in at the front desk.)

3. The contact person will meet you and accompany you to the oral health screening area.

4. The subjects and/or their guardians who have completed and returned a **signed** consent form will be brought to the screening area by facility site staff. Each subject's completed and signed consent form will be handed to the recorder by facility site staff when it is the subject's turn to be screened. Be sure to verify that the consent form has been signed.

5. Be sure to write the subject's name on the top right hand corner of the Treatment Urgency Form. (These forms will be given to the facility site staff at the conclusion of the screening.)

6. Please dispose of mouth mirrors, gloves, facemasks and cotton tipped applicators in the trash bag marked with a Biohazardous Waste sticker. This is to eliminate the possibility of subject's retrieving any of the used materials. At the end of the day make sure the trash bags are disposed of in an appropriate manner as they are marked with a Biohazardous Waste sticker.

7. It is anticipated that the oral health screening will take 15-20 minutes per subject.

8. After all subjects with signed consent have been screened, the facility contact person will escort you from the facility.

    - **EVERY** subject receives a toothbrush and toothpaste whether or not they were screened. Check with the site staff to see how they would like these distributed.

The UNLV School of Dental Medicine and the Nevada State Health Division Oral Health Program thanks you for volunteering your time and assisting in this important oral health screening for the benefit of Nevada's special needs population.

Letter of Authorization to Conduct Research at Facility

Correspondence must be on the facility's letterhead

[cut and paste all below to your document]

Brenda Durosinmi, MPA, CIP, CIM -Director
Office for the Protection of Research Subjects
University of Nevada Las Vegas
4505 Maryland Parkway Box 451047
Las Vegas, NV 89154-1047

Subject: Letter of Authorization to Conduct Screenings at Desert Regional Center.

Dear Ms. Durosinmi:

This letter will serve as authorization for the University of Nevada, Las Vegas ("UNLV") School of Dental Medicine oral health screening team, Dr. Mildred A. McClain, Dr. R. Michael Sanders, dental faculty, and 3rd and/or 4th year dental student doctors to conduct the oral health screening project entitled Governor's Commission Oral Health Screening on Special Needs Population at Desert Regional Center, (the "Facility").

The Facility acknowledges that it has reviewed the protocol presented by the screening team, as well as the associated risks to the Facility. The Facility accepts the protocol and the associated risks to the Facility, and authorizes the screening project to proceed. The screening project may be implemented at the Facility upon approval from the UNLV Institutional Review Board.

If we have any concerns or require additional information, we will contact the screening team and/or the UNLV Office for the Protection of Research Subjects.

Sincerely,

_____ _____

Facility's Authorized Signatory Date

_____

Printed Name and Title of Authorized Signatory

UNLV
CELEBRATING FIFTY YEARS

Biomedical IRB – Exempt Review
Approved as Exempt

Office for the Protection of Research Subjects
UNLV IRB
Approved
SEP 10 2007
Expires

DATE: September 10, 2007

TO: **Dr. Millie McClain,** School of Dental Medicine

FROM: Office for the Protection of Research Subjects

RE: Notification of IRB Action by Dr. John Mercer, Chair JM/09
Protocol Title: **Governor's Commission Oral Health Screening on Special Needs Population**
OPRS# 0706-2399

This memorandum is notification that the project referenced above has been reviewed by the UNLV Biomedical Institutional Review Board (IRB) as indicated in Federal regulatory statutes 45CFR46.

The protocol has been reviewed and deemed exempt from IRB review. It is not in need of further review or approval by the IRB.

The review of this protocol is limited to the review of activities associated with the research study - not the service/educational activities.

Since the verbal script is focused on verbally explaining the service/educational program, the verbal script is not part of the review.

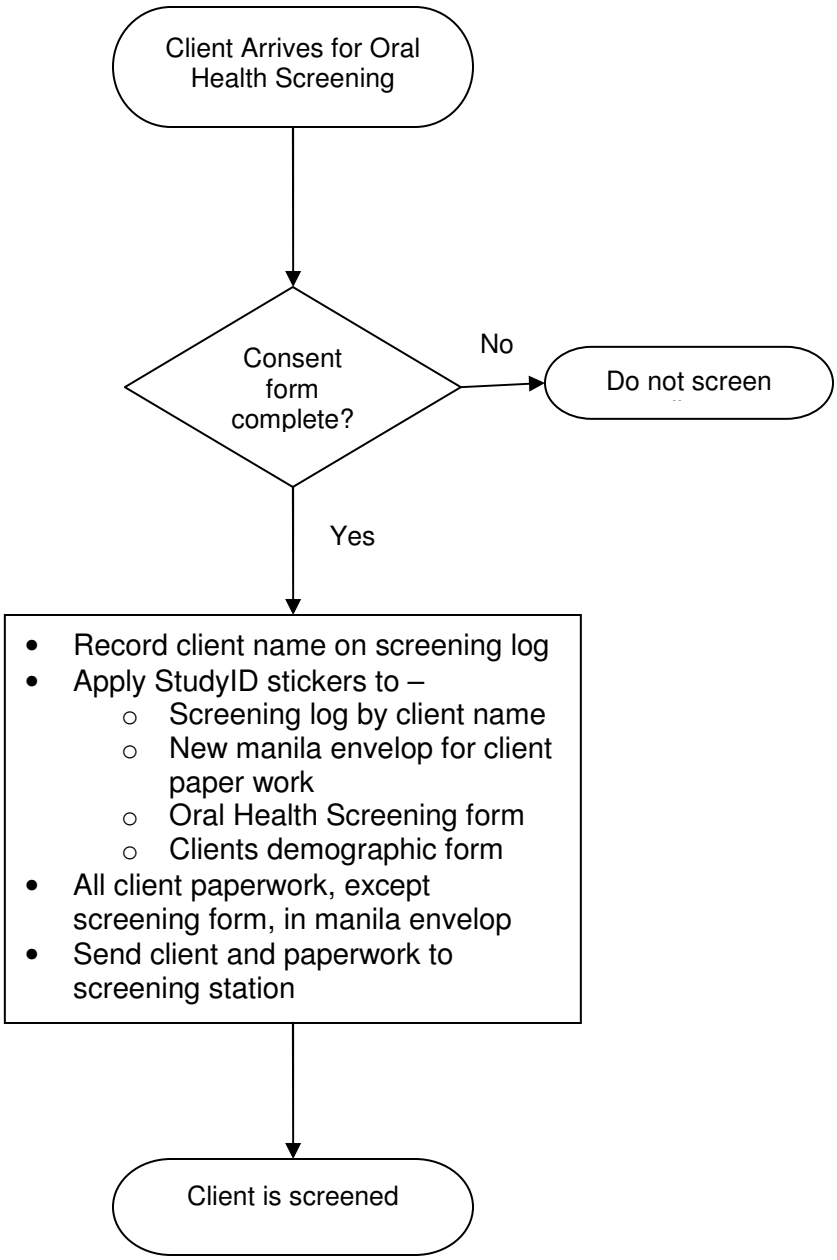
PLEASE NOTE:
Attached to this approval notice is the **official Informed Consent/Assent (IC/IA) Form** for this study. The IC/IA contains an official approval stamp. Only copies of this official IC/IA form may be used when obtaining consent. Please keep the original for your records.

Any changes to the exempt protocol may cause this project to require a different level of IRB review. Should any changes need to be made, please submit a **Modification Form**.

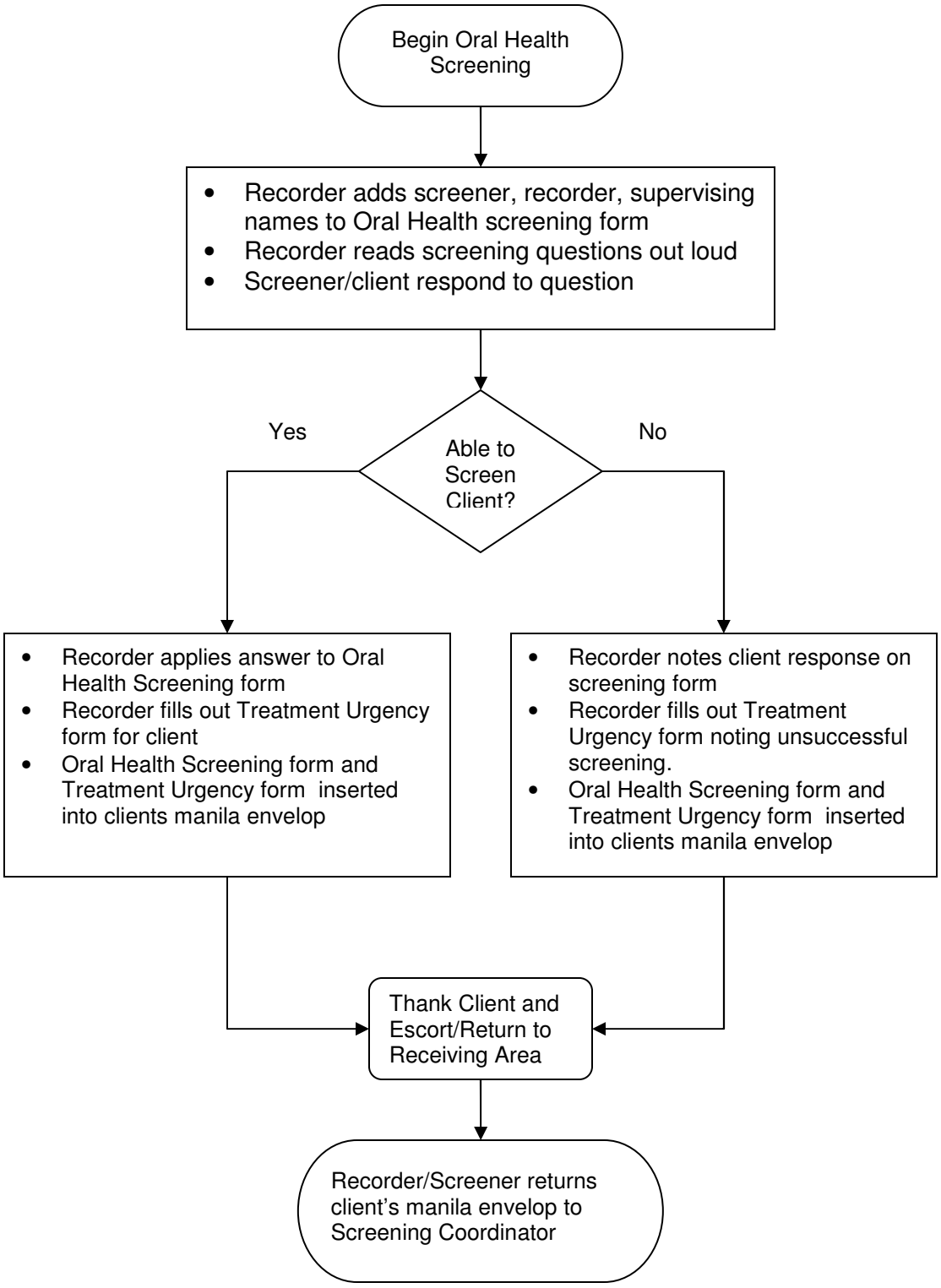
If you have questions or require any assistance, please contact the Office for the Protection of Research Subjects at OPRSHumanSubjects@unlv.edu or call 895-2794.

Office for the Protection of Research Subjects
4505 Maryland Parkway • Box 451047 • Las Vegas, Nevada 89154-1047
(702) 895-2794 • FAX: (702) 895-0805

Oral Health Screening Flow Arrival Process



Oral Health Screening Flow
Screening Process



Nevada 2007 Oral Health Basic Screening Survey
- Special Needs Population -
Evaluation Report

The process evaluation of Nevada's 2007 – Oral Health Basic Screening Survey (BSS) of adults with developmental disabilities and/or mental illnesses consisted of two parts:

Part 1: Upon completion of the screenings, three separate interview sessions were scheduled with the organizations who partnered with Nevada's Oral Health Program in conducting the BSS oral health screenings. *"Attachment A"* outlines the meeting format and the feedback received from partners during the meetings.

Form A: Meeting Outline
Form B: BSS Timeline

Part 2: Participating dental students were asked to complete a Screener/ Recorder Questionnaire. *"Attachment B"* reports the dental students' responses.

Form C: Special Needs Basic Screening Survey – Screener/Recorder Questionnaire

Evaluation Findings:

Feedback from the partnering organizations and dental students indicated that it was primarily a positive experience conducting the BSS of adults with special needs due to developmental disabilities and/or mental illnesses. Partners were in agreement about the primary purpose of the screenings; to obtain some baseline data of oral health needs within the screened population, to offer the dental students experience with the patient population, to be able to utilize data obtained to advocate for preventive care and dental treatment for individuals with developmental disabilities and mental illnesses and to provide a brief, positive dental experience for those screened, i.e., for desensitization.

Areas that could be improved, based on feedback from partners; consulting end-users and their primary caregivers for most feasible timing and location of the screenings, developing an incentive program for participating in the screening, providing adequate lead time for obtaining participation consent forms and/or incorporating them into existing annual family/guardian sessions, identifying reasonable follow-up care plans and involving any public or patient advocates in the planning process. The effort and time needed to complete the IRB process impacted all of the partnering agencies and it is hoped that any future screenings would be easier to conduct utilizing an extension, or an addendum, to the existing IRB. In order to expand the depth and breadth of the screening project, investigate ways to incorporate oral health screenings of severely mentally ill

adults as well as expand the sample size of individuals with developmental disabilities who also have co-occurring conditions, i.e., cerebral palsy.

Feedback from the dental students who helped screen or record patient data revealed that 73 percent of the students indicated that it took, on average, five minutes or less to screen each patient. None of the students stated that the average screening time was more than nine minutes. Ninety percent of dental students felt fully prepared by the calibration session and their dental education to perform the screenings. All the screener/recorder questionnaires stated that the form prepared for recording the data was easy to use. Only 13 percent of students disagreed that the experience would help them feel more comfortable and/or better prepared to treat the oral health needs of individuals with developmental disabilities or mental illness. A large majority (83%) of the dental students said that they would participate in this screening again.

Partners were very appreciative of the time and skills of the Oral Health Program's Screening Coordinator. Her efforts were identified as being a large contributor to the success of the project; keeping the communication flowing and helping the partners with reminders for next steps. The partners agreed that it was an involved process, which required quite a bit of time and effort, nevertheless it would be worthwhile if the results were utilized to improve access to dental care for adults with developmental disabilities or mental illness.

Partner Interview Session Feedback

Description: On December 19, 2007, three separate meetings were held with the organizations who partnered with Nevada's Oral Health Program in conducting an open-mouth, oral health screening of adults with developmental disabilities and/or mental illnesses; UNLV School of Dental Medicine (UNLV SDM), Desert Regional Center (DRC) and Rawson Neal Psychiatric Hospital (RNPH).

Meeting Attendees: Meetings were facilitated by the Evaluation Consultant (EC) with Nevada State Health Division's Oral Health Program. In addition to the EC the program's Biostatistician and Fluoridation Specialist/Oral Health Screening Coordinator participated in the three meetings. Attendees representing the three partnering agencies were:

UNLV SDM	DRC	RNPH
• Dr. Mildred McClain • Connie Mobley	• Susan Yates–Chambers • Winnie Wong	• Mary Jo Solon, RN • James Vilt, MD (Psychiatrist, Medical Director)

Purpose of Meetings: Utilizing a written meeting outline (Form A), key participants were asked to review the screening planning process and implementation. Attendees identified what worked well, what needed improvement and discussed the lessons learned about planning and managing the recent oral health survey. Lessons learned can be utilized by the Nevada State Oral Health Program and others to prepare for and conduct future oral health surveillance projects.

Partner Feedback:

I. Attendees reviewed a timeline (Form B) of the significant milestones, events, and issues that occurred during the project. Meeting attendees were asked to note if there was anything missing, needing editing or that required an explanation.

UNLV SDM	DRC	RNPH
• It was noted that the UNLV SDM course on special needs populations was already on the books and the timeline was edited accordingly.	• No edits suggested.	• No edits suggested. • (It should be noted that due to a number of staffing changes at RNPH, both of their representatives present at the project review meeting were hired well after the planning process was underway.)

II. In response to the questions, "What did you perceive as the PRIMARY PURPOSE of the oral health screening?" and "Can you identify any other purposes of conducting the screening? If yes, what were they?" The attendees replied:

UNLV SDM	DRC	RNPH
• Establishing baseline or preliminary data for seeking future funding to treat the oral health needs of the specific population. • Identifying the proportion of the special needs population that would need specialty care (anesthesia, etc.) and what proportion could feasibly be treated by general dentists. • Increasing dental student comfort-level with the population as well as their awareness of the dental needs of the special needs population. • Increasing the level of awareness of the special needs population and their caregivers to the specific oral health needs.	• To find out how much need for oral health services there was (especially in the community). • To have data to advocate for Medicaid funded dental services for this population. • To help the dental students get an objective view of the type of people that are served there, with the hope of decreasing fears and increasing the access to care for the population.	• To develop some kind of thought on the prevalence of dental issues for this patient population. • To offer the dental students the opportunity to work with the patient population that they may not always have exposure to while they are students. • If a sizeable population of patients are identified in need of dental work, to be able to seek grants in the future to serve the people

III. Do you feel the screening process was well ORGANIZED?

UNLV SDM	DRC	RNPH
• As far as RNPH they had the room ready, the patients ready and everything went smoothly. • For DRC: Having it on-site allowed them to back-fill with campus residents when community residents were no-shows. No-shows or very small participant groups were a problem.	• Millie was extremely organized. • UNLV SDM was able to leave their equipment in a locked closet on site in between screening dates.	• The screening process itself went quite well. • It did not take as long to screen each patient as initially planned. • Plans to have more staff on duty to run patients back and forth worked well.

a) What could improve the process?

UNLV SDM	DRC	RNPH
• Weekday screenings would probably work better for dental student recruitment and to avoid conflict with the schedules of the DRC clients. • Having contact information to follow up with the group	• Getting the consent forms months ahead of time to be able to orient people and get signed forms returned. • Utilizing annual meetings with the individuals and their families/guardians to get	• None noted.

homes – for reminders or to follow up on no shows. • Having existing IRB that can be extended if for the same population and purpose. An addendum to the IRB could be done if there were slight changes.	consent forms signed that could be valid for a year at a time. • Increased awareness of the schedules of the individual's being screened – Screening was scheduled (inadvertently) during the middle of a very popular activity –bowling league and tournaments. • Incentives for participation – i.e., certificates for dental cleaning, etc.	

IV. Was participating in the oral health screening VALUABLE to your organization in any way?

UNLV SDM	DRC	RNPH
• As far as the 4th year students go, a lot of them had not been exposed to someone from this population and didn't know how to interact with them. The dental students that were kind of fearful maybe got a little bit of that "fear factor" taken away.	• Yes, for obtaining a clear understanding of the dental needs of the population.	• Participating opened up an opportunity to have discussions with the nursing staff about IRB's and research studies as well as informed consent and who can offer it.

a) Was it worth the time and effort for your organization to participate in the screening?

UNLV SDM	DRC	RNPH
• [No record of question asked, or answered.]	• It depends if positive results are seen.	• I think it was worth the time and effort. • I think as we go through the process in the future it will be a little simpler. Even our second Saturday went easier than our first one. • It took quite a bit of time and effort.

V. Do you feel the screening is important for MEASURING THE ORAL HEALTH of individuals with special needs?

UNLV SDM	DRC	RNPH
• I think we could have had a better mixture. (i.e.,	• Yes, we had a wide variety of people	• Only those healthy enough to give informed consent were

additional clients with co-occurring conditions such as cerebral palsy, etc. and the medication issues associated.) • Also the sample sizes were too small to extrapolate anything. • The convenience sample will give us some information.		screened. • Ideally…everybody would get screened because, unfortunately, the sickest people probably have the sickest mouths. • It is a patient population that includes many people who have never been to the dentist.

a) Any suggestions of additional ways to access and measure the oral health of this population?

UNLV SDM	DRC	RNPH
• As suggested by DRC, utilizing the day programs.	• Transportation conflicts could be eased by incorporating screenings such as this into the normal schedules of the community – i.e., at Day Programs such as Opportunity Village.	• None noted.

VI. What kind of FEEDBACK did you receive from individuals with specials needs, or their primary caregivers, about the screening?

UNLV SDM	DRC	RNPH
• The only feedback received was at RNPH. Thirty clients were scheduled for the first Saturday and eight thought they were getting cleanings and dropped out when they found out they were not.	• No feedback received in regards to campus residents. • Many of the community providers and some clients expressed feeling they don't see any benefit from taking the clients to the screening, if no other services were being offered. • There were some clients who said they had very positive experiences – the students were nice to them and the individual enjoyed this activity – so they had a "positive dental experience" to remember.	• We had some people that consented and then refused to come that morning. The refusal was tied to their desire for treatment, i.e., a cleaning. • Some patients expressed that they would rather not know they had a problem, if they cannot get it fixed. • Lack of follow-up care resources was frustrating. If we find a need while they are here does it put the hospital on the hook to have that included into the patient's discharge plan?

VII. Identify and list reasons for NONPARTICIPATION at the individual level.

UNLV SDM	DRC	RNPH
• Transportation. • Because of other activities	• The process to complete and return the consent forms was	• Patients that we were able to select for the screenings were

scheduled during the same time or on the same day. • Lack of perceived value, if no other services were being provided.	too cumbersome for the providers. • Lack of perceived benefit for screening without additional services offered.	a definite sub-set of our patient population. We did not select any patients who were actively psychotic or had other explosive behaviors. Only patients with the most stable behavior were selected. • Timing a consent form to be completed and returned during the time the patient was hospitalized – average stay is 21 days. • Lack of perceived benefit for screening without additional services offered.

a) Did (self-selected) nonparticipation by individuals result in any groups being under or over-represented?

UNLV SDM	DRC	RNPH
• n/a	• No.	• Yes, see above.

b) Did nonparticipation by groups of individuals impact the quality of any data collected?

UNLV SDM	DRC	RNPH
• See VI.	• N/A	• Because this is a convenience sample it may still be useable, however it is definitely not reflective of the sickest individuals.

VIII. To what degree were individuals comfortable with the research process and felt that they were research partners rather than "research subjects"?

UNLV SDM	DRC	RNPH
• n/a	• This was not a problem.	• No negative impact noted.

IX. To what extent do you feel the Oral Health Program staff met your expectations for supporting a successful surveillance project?

UNLV SDM	DRC	RNPH
• I think it was great. Lori got on the phone and all the email reminders and so forth.	• They were very successful in getting us what we needed; we just couldn't get it quick enough because somebody put up a road block.	• Lori was very well organized and she kept us all on track. It was very helpful for me. Lori was the glue that made it all work.

X. Review Lessons Learned:

a) What was done well?

UNLV SDM	DRC	RNPH
• The collaboration part worked well between the Oral Health Program and the Dental School. • With RNPH they had their own thing, but once they got the training done it went well. • The numbering format to ensure confidentiality worked well.	• For campus residents it worked well having it on site. • From what I heard the people were well respected. • Once screening was in process, it went well. • Paula Rahm talked to the dental students ahead of time to orient them on the population.	• See IX. • We aimed for fifty and we got thirty-nine, so it was pretty good.

b) What was learned?

UNLV SDM	DRC	RNPH
• With DRC it was a little bumpy because they had other variables in the mix such as the advocates. • Talk to the end-user. We need their involvement for scheduling. Make sure we have contact information – we had phone numbers of the nurses at DRC, but not the group homes. • Being able to store the equipment at the site – that worked fantastic.	• Saturday schedule for community residents and dental students did not work as well as expected. • Transportation is problematic. Incorporating the screening into existing day programs could make it easier for clients/caregivers and increase participation.	• Our first Saturday was right after the Thanksgiving Holiday and our treatment teams did not meet as frequently so it was harder to get the consents completed. • Originally I thought Saturday's would work better, but any day during the week should work.

c) What needs improvement?

UNLV SDM	DRC	RNPH
• Increase end-user input to screening design/scheduling.	• Incentives • Paperwork available and completed ahead of time.	• Referrals for follow-up care.

d) What needs further discussion?

UNLV SDM	DRC	RNPH
• How to access a comprehensive cross-section of the population in order to provide weight to the findings.	• Make sure data is going to get to somebody who is going to make a difference. Ensure data is shared with the right people with the	• n/a

	right goals in mind.	

e) Any solutions?

UNLV SDM	DRC	RNPH
• Identify partners and funding streams to increase access to follow-up care for population screened.	• Mobile program through dental school or other partners to treat identified dental needs.	• n/a

XI. Any additional comments?

UNLV SDM	DRC	RNPH
• Millie's hoping to write a report on the experience. • Connie suggested part of it should be recommendations based on this "snapshot" of this population. • Jim will attempt to compare data collected to state data and national data for adults, when possible. • OHP staff asked for lists of students and staff names for acknowledgement in our report.	• Jim will send report to partners before publishing. • Winnie suggested having provider's names in report.	• Thought it was a very positive experience.

Additional notes:

Desert Regional Center is a state agency that provides services to both adults and children with developmental disabilities. A variety of services are offered in their effort to help people gain life choices, independence, and participation in the community.

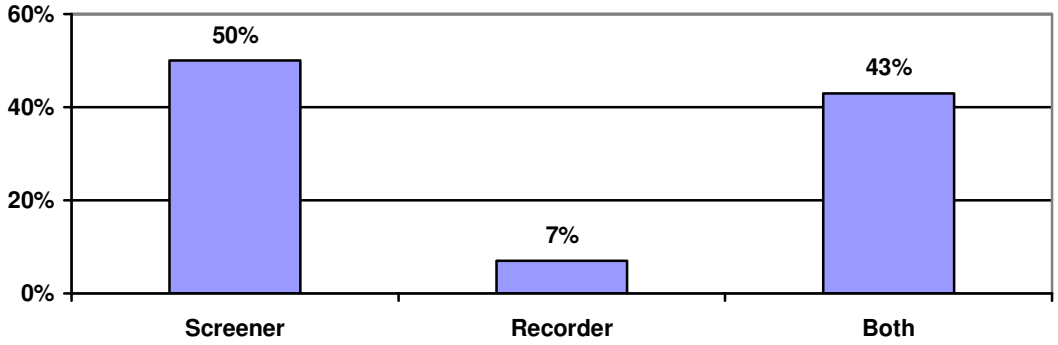
Opportunity Village is a not-for-profit organization that serves people with developmental disabilities by providing them with vocational training, employment and social recreation services that make their lives more productive and interesting. Through Opportunity Village's programs and services, hundreds of people with disabilities are learning vocational skills and being placed in jobs throughout the community.

Special Needs Basic Screening Survey
Screener/Recorder Questionnaire

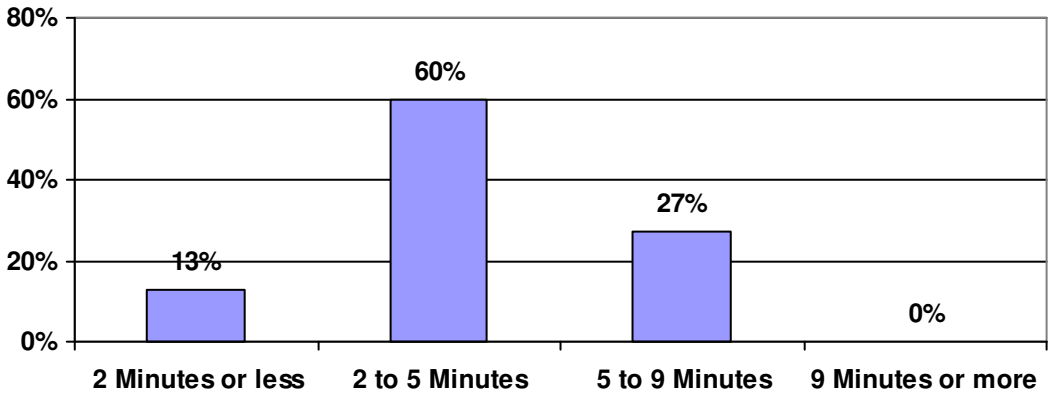
1. Are you a third or fourth-year dental student

100% 4th Year Students

2. During the screening did you perform the duties of: ❑ Screener ❑ Recorder ❑ Both

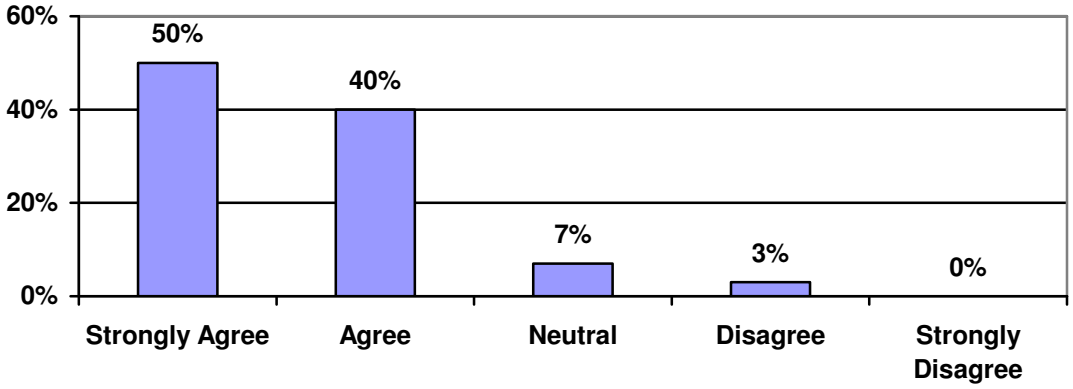


3. Please indicate the average length of time it took to screen one individual.

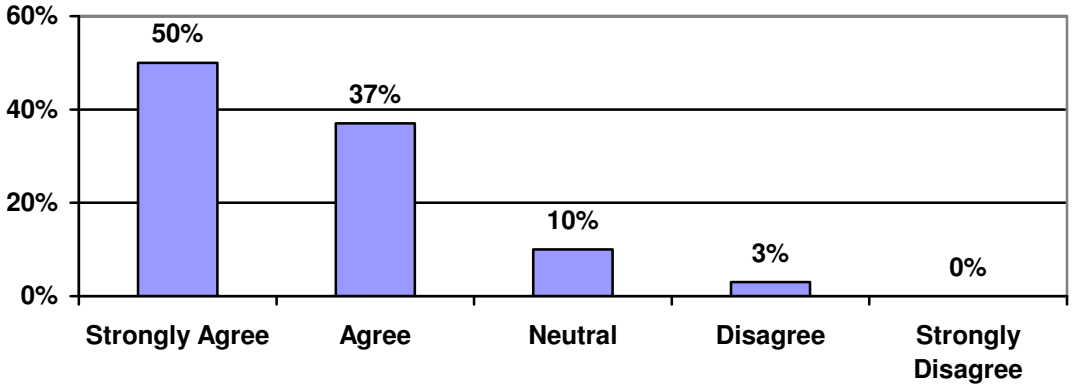


On items 4 through 8 please indicate your level of agreement with each statement.

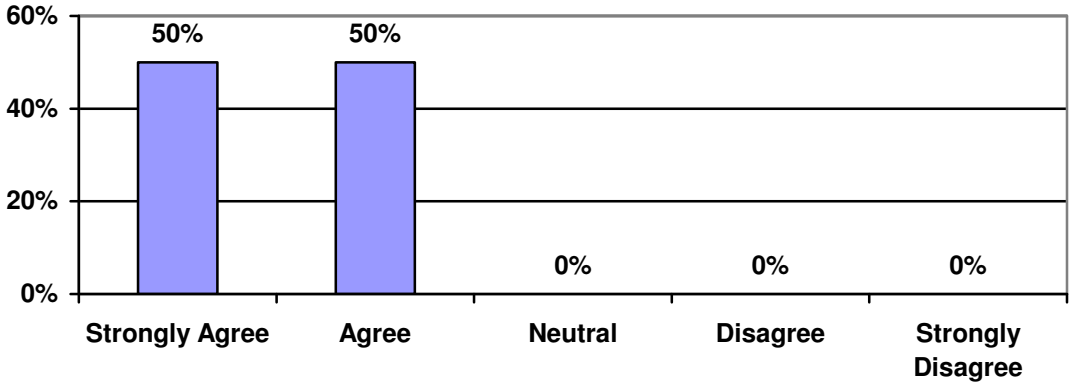
4. I feel the calibration session and my dental education fully prepared me to screen the individuals with special needs.



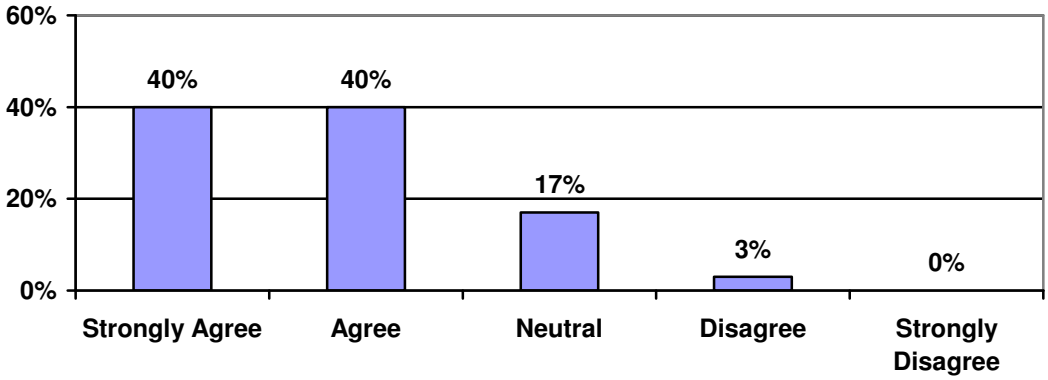
5. The equipment provided to perform the screening was sufficient. (i.e., gloves, disposable mirrors, flashlights, masks, cotton tip applicators)



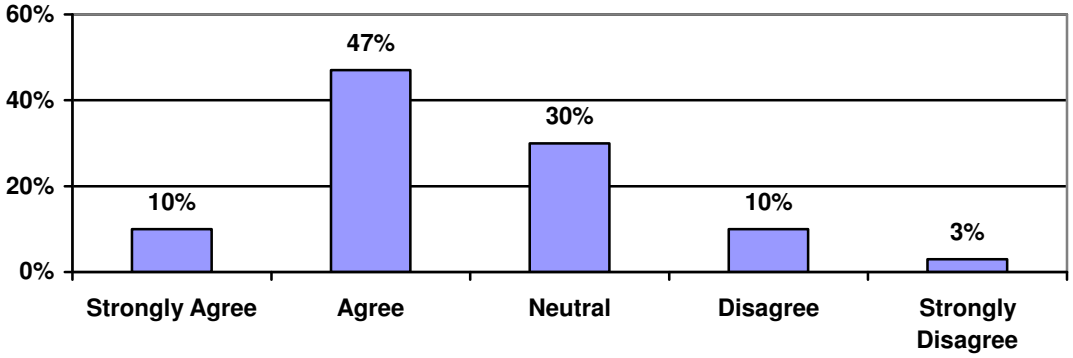
6. The form prepared for recording data was easy to use.



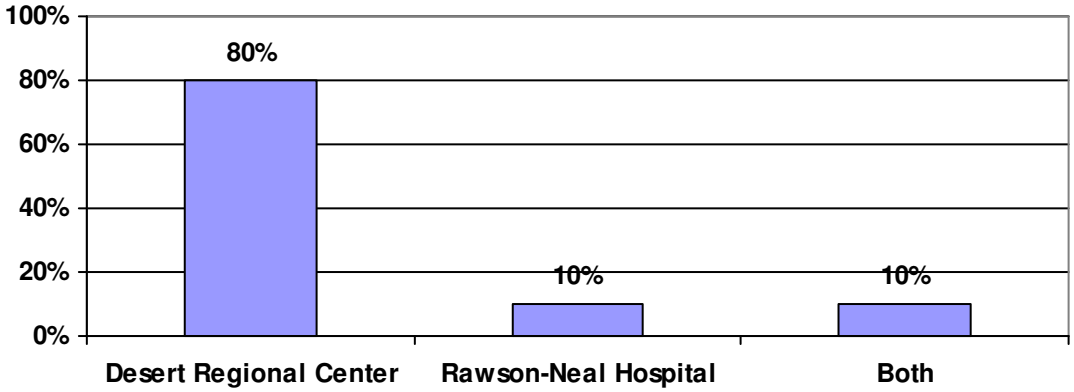
7. I feel the screening was important for measuring the oral health of individuals with special needs.



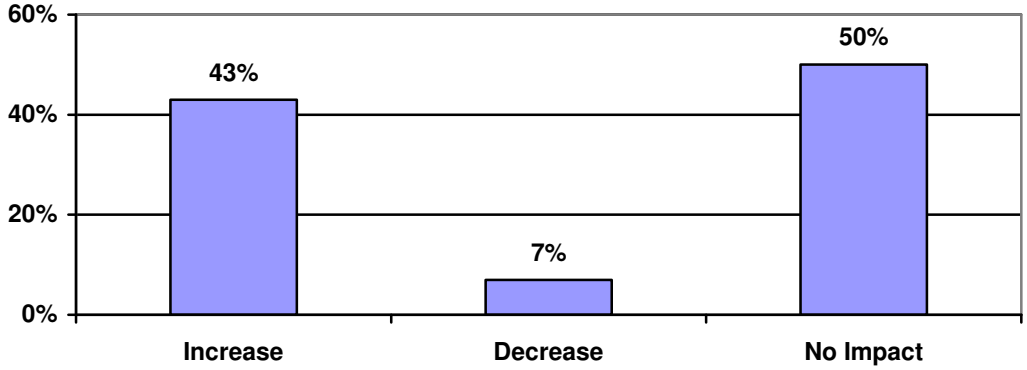
8. I feel this screening experience will help me to feel more comfortable and/or better prepared to treat the oral health needs of individuals with special needs.



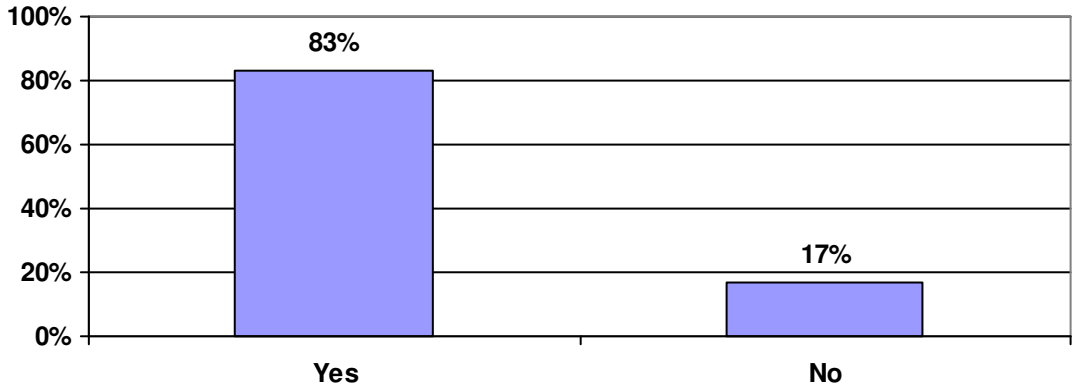
9. At which facility did you participate in the oral health screenings?



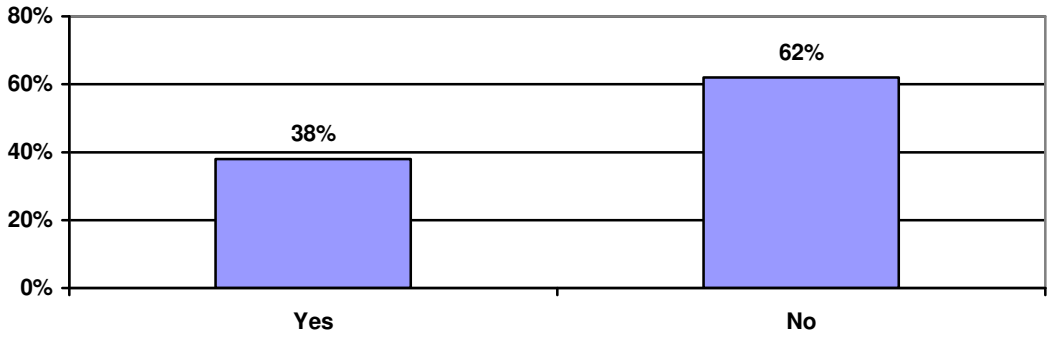
10. Did your experience with the screening increase, decrease or have no impact on your desire to treat this population?



11. Would you participate in this screening again?



12. Is there anything we can do to improve the process in conducting the oral health screening?



Oral Health Surveillance Survey 2007
- Special Needs Population -
Project Reflection – Meeting Outline

Purpose of meeting: We are seeking to conduct a review of the planning and process of managing the recent oral health survey of adults with special needs. Lessons learned can be utilized by the Nevada State Oral Health Program and others to prepare for and conduct future oral health surveillance projects.

I. **Create a timeline of the significant milestones, events, and issues that occurred during the project.**
   a) **Review drafted timeline.**
   b) **Is anything missing, need editing or require an explanation?**

II. **Discussion:**
   a) **What did you perceive as the PRIMARY PURPOSE of the oral health screening?**
   b) **Can you identify any other purposes of conducting the screening? If yes, what were they?**

III. **Discussion: Do you feel the screening process was well ORGANIZED? What could improve the process?**

IV. **Discussion:**
   a) **Was participating in the oral health screening VALUABLE to your organization in any way?**
   b) **If so, how?**
   c) **Was it worth the time and effort for your organization to participate in the screening?**

V. **Discussion:**
   b) **Do you feel the screening is important for MEASURING THE ORAL HEALTH of individuals with special needs?**
   c) **Any suggestions of additional ways to access and measure the oral health of this population?**

VI. Discussion: What kind of FEEDBACK did you receive from individuals with specials needs, or their primary caregivers, about the screening?

VII. Discussion:

c) Identify and list reasons for NONPARTICIPATION at the individual level.

d) Did (self-selected) nonparticipation by individuals result in any groups being under or over-represented?

e) Did nonparticipation by groups of individuals impact the quality of any data collected?

VIII. Discussion: To what degree were individuals comfortable with the research process and felt that they were research partners rather than "research subjects"? (Rating scale: 1 = extremely uncomfortable to 5 = extremely comfortable)

IX. Discussion: To what extent do you feel the Oral Health Program staff met your expectations for supporting a successful surveillance project? (Rating scale: 1 = Fully unsuccessful in meeting expectations to 5 = Fully successful in meeting expectations)

X. Review Lessons Learned:

f) What was done well?

g) What was learned?

h) What needs improvement?

i) What needs further discussion?

j) Any solutions?

XI. Any additional comments?

Thank you for your time and your valuable input.

Special Needs Screening Timeline

May 2005 –OHAC established a workgroup to look at improving services for special needs populations.

May 2006 – OHAC workgroup began working with Governor's Commission on Mental Health and Developmental Services.

Fall 2006 - A dental workforce survey that included some questions about treating clients with special needs was created and sent out to all dentists with an active Nevada license. (Report published in October 2007)

April 17, 2007 –OHP staff met with special needs committee consisting of:
Patty Craddock, DDS – Nevada Dental Association
Steve Hackmyer, DDS - UNLV SDM
Nancy Knox, Director, DRC
Millie McClain, PhD –UNLV SDM
Connie Mobley, PhD - UNLV SDM
Rena Nora, MD – Governor's Commission on Mental Health and Developmental Services
Michael Sanders, DMD, EdM - UNLV SDM
Chris Wood, RDH – Oral Health Program Manager, Nevada State Health Division (NSHD)

*Notes were provided to those attending the meeting.

May 16, 2007 – Meeting at DRC
Deborah Aquino, NSHD, OHP
Susan Yates-Chambers, R.N., DRC
Lori Cofano, RDH, NSHD, OHP
James Jordan, NSHD, OHP
Nancy Knox, DRC
Dr. Mildred McClain, UNLV SDM

Discussed number of portable chairs, number of clients to be screened, amount of time needed to screen, location for screenings, forms needed, and days to screen (Saturdays). It was agreed that Dr. McClain, Susan, and Nancy would review the forms and advise the OHP of any other changes no later than Wednesday, May 30th.

*Notes were provided to those attending the meeting.

May 24, 2007 – Meeting at RNPH
Deborah Aquino, NSHD, OHP
Lori Cofano, R.D.H., NSHD, OHP
James Jordan, NSHD, OHP

Dr. Mildred McClain, UNLV SDM
Belinda Perez, R.N., Interim Director of Nursing, RNPH

Ms. Perez explained the she would not make the decision as to whether RNPH would participate. Dr. Ghertner would make that final decision.
Ms. Perez felt that Saturdays or Sundays between 10:00 am and 2:30 pm would work for screening. OHP staff was informed that the average stay for patients is 21 days. Each patient's psychiatrist would determine if they were eligible to participate in the screening.

* Notes were provided to those attending the meeting and to Dr. Nora.

May 31, 2007 – Dr. Ghertner contacted Lori Cofano to discuss his concern about RNPH not having a Director of Nursing or a Medical Director. He wanted to know if the screenings could be postponed until the spring. He felt there were too many issues and too much work would be required of RNPH staff.

June 5, 2007 – Dr. Ghertner contacted Lori Cofano to let her know that a new Director of Nursing (DON) had been hired at RNPH and that she was in orientation this week. He agreed to allow one pod (approximately 40 patients) at RNPH to be screened. Lori requested a meeting with the new DON be scheduled for June 12 between 3:30 and 4:00 as she would already be in Las Vegas.

June 6, 2007 – Demographic and screening forms finalized and sent to workgroup for review.

June 12, 2007 – Meeting at RNPH
Lori Cofano, RDH, NSHD
Mary Jo Solon, RN, Director of Nursing, RNPH

Ms. Solon had just started working as the Director of Nursing at RNPH.
Discussion centered on protocol to be followed during screenings at RNPH.

June 2007 – Institutional Review Board (IRB) paperwork begun

June 26, 2007 – IRB proposal submitted

June 26, 2007 – Conference call to discuss screenings at RNPH
Lori Cofano, RDH, NSHD, OHP
James Jordan, NSHD, OHP
Dr. Mildred McClain, UNLV SDM
Rena Nora, MD – Governors Commission on Mental Health and Developmental Services
R. Michael Sanders, DMD, EdM - UNLV SDM
Mary Jo Solon, RN, Director of Nursing, RNPH

Discussed IRB. Dr. Nora offered Mary Jo her assistance in getting the screenings approved at RNPH. Referral process discussed. Timeframe, dress code and orientation of dental students was discussed.

* Notes were provided to those who participated in conference call as well as contact information.

July 10, 2007 – Mary Jo contacted Lori Cofano regarding concerns about screenings. Concerns included: can their patients actually consent to screening; how will follow-up be handled; if suspicious lesion is found patients can't get out for treatment; only way to receive treatment is transportation via ambulance to University Medical Center; cost of treatment liability.

July 11, 2007 – Dr. Nora called about current situation of screenings at RNPH. Lori discussed Mary Jo's concerns and Dr. Nora said she would contact their legal counsel for advice.

July 16, 2007 – Dr. McClain received letter from RNPH for IRB packet however; RNPH wanted a confidentiality agreement included.

July 24, 2007 – UNLV IRB meeting

August 2007 – Began to order screening supplies

August 22, 2007 – Exempt Research Application Form submitted to UNLV IRB

August 29, 2007 – Meetings at:

UNLV SDM
Lori Cofano, RDH, NSHD, OHP
Dr. Marcia Ditmyer, UNLV SDM
James Jordan, NSHD, OHP
Dr. Mildred McClain, UNLV SDM
Dr. Connie Mobley, UNLV SDM
Dr. Michael Sanders, DMD, UNLV SDM

Discussed flow of forms; schedule for DRC and RNPH; who will oversee the code sheet.

DRC
Susan Yates-Chambers, RN, Director of Nursing, DRC
Lori Cofano, RDH, NSHD, OHP
Lottie Horton, Program Coordinator, on campus, DRC
James Jordan, NSHD, OHP
Nancy Knox, Regional Director, DRC
Dr. Mildred McClain, UNLV SDM
Nechia Odunze, Service Coordinator, DRC

Tom Smith, Director of Residential Services, DRC
Winnie Wong, Community Service Supervisor, DRC
Discussed scheduling, transportation, patient cooperation, forms, cancellations, and dental student orientation.

RNPH
Lori Cofano, RDH, NSHD, OHP
James Jordan, NSHD, OHP
Mary Jo Solon, RN, Director of Nursing, RNPH
Discussed schedule, cancellations, screening location, patient cooperation, forms, guidelines, and dental student orientation.

* Notes were sent out to those attending each of these meetings.

September 10, 2007 – Received IRB approval with exemption

September 19, 2007 – Calibration session for UNLV SDM dental students

September 22, 2007 – Screenings began at DRC

December 1, 2007 – Screenings began at RNPH

December 19, 2007 – Evaluation meetings at DRC, UNLV SDM, RNPH

Special Needs Basic Screening Survey
Screener/Recorder Questionnaire

Thank you for assisting with the recent open-mouth screening of individuals with special needs. In order to continuously improve our efforts, we ask that you take a few minutes and complete the following questionnaire about your experience with the Basic Screening Survey.

5. Are you a third or fourth-year dental student? _____-year

6. During the screening did you perform the duties of: ❑ Screener ❑ Recorder ❑ Both

7. Please indicate the average length of time it took to screen one individual.

❑ 2 minutes or less
❑ More than 2 minutes, but not more than 5 minutes
❑ More than 5 minutes, but not more than 9 minutes
❑ More than 9 minutes, but not more than 12 minutes
❑ More than 12 minutes, but not more than 15 minutes
❑ More than 15 minutes

<u>On items 4 through 8 please indicate your level of agreement with each statement.</u>

8. I feel the calibration session and my dental education fully prepared me to screen the individuals with special needs.

❑ Strongly Agree ❑ Agree ❑ Neutral ❑ Disagree ❑ Strongly Disagree

5. The equipment provided to perform the screening was sufficient. (i.e., gloves, disposable mirrors, flashlights, masks, cotton tip applicators)

❑ Strongly Agree ❑ Agree ❑ Neutral ❑ Disagree ❑ Strongly Disagree

6. The form prepared for recording data was easy to use.

❑ Strongly Agree ❑ Agree ❑ Neutral ❑ Disagree ❑ Strongly Disagree

7. I feel the screening was important for measuring the oral health of individuals with special needs.

❑ Strongly Agree ❑ Agree ❑ Neutral ❑ Disagree ❑ Strongly Disagree

8. I feel this screening experience will help me to feel more comfortable and/or better prepared to treat the oral health needs of individuals with special needs.

❑ Strongly Agree ❑ Agree ❑ Neutral ❑ Disagree ❑ Strongly Disagree

9. At which facility did you participate in the oral health screenings?

❑ Desert Regional Center ❑ Rawson-Neal Hospital ❑ Both

10. Did your experience with the screening increase, decrease or have no impact on your desire to treat this population?

❑ Increase ❑ Decrease ❑ No Impact

11. Would you participate in this screening again?

❑ Yes ❑ No *Please explain.* _____

_____

_____

_____

12. Is there anything we can do to improve the process in conducting the oral health screening?

❑ Yes ❑ No *Please explain.* _____

_____

_____

_____

Additional comments:

_____

_____

_____

_____

Thank you for your participation!

Please return completed questionnaires to:
Dr. McClain